

EXHIBIT 1

1 IN THE CIRCUIT COURT OF JASPER COUNTY, MISSOURI

3

6 v.

8 FREEMAN HEALTH SYSTEM d/b/a •

10 HEALTH SYSTEMS, ETHICON, INC., •

12 a division of Ethicon, Inc., •

14 Defendants. •

16 VIDEOTAPED DEPOSITION OF NICOLETTE HORBACH, M.D.

18 August 21, 2013

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22 Pages 1-323

24 Video Specialist: Michael Gay, CLVS

Nicolette S. Horbach, M.D.

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The following is the videotaped deposition of
NICOLETTE HORBACH, M.D. held at the offices of:

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O'Melveny & Myers LLP

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1625 Eye Street, N.W.

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Washington, DC 20006

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Taken pursuant to applicable Rules of Civil
Procedure, before Linda S. Kinkade, Registered
Diplomate Reporter, Certified Realtime Reporter,
Registered Professional Reporter, Registered Merit
Reporter, Certified Shorthand Reporter, and Notary
Public, in and for the District of Columbia.

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Nicolette S. Horbach, M.D.

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Nicolette S. Horbach, M.D.

1 P R O C E E D I N G S

2 VIDEO SPECIALIST: We are on the
3 record. The time now is 10:24. This marks the
4 beginning of disc number 1 in the videotaped
5 deposition testimony of Dr. Nicolette Horbach in
6 the matter of Schubert versus Ethicon, et al.

7 This case is pending in the Circuit Court
8 of Jasper County, Missouri at Joplin, case number
9 10 AO-CC 00219. Today's date is August the 21st,
10 2013. This deposition is being conducted at 1625
11 Eye Street, northwest, Washington, D.C.

12 Will all attorneys present please identify
13 themselves and who they represent.

14 MR. SLATER: Adam Slater on behalf of
15 the plaintiffs.

16 MS. JONES: Christy Jones on behalf of
17 Ethicon and J&J, Johnson & Johnson.

18 MR. OVERBY: David Overby on behalf of
19 Freeman Health System.

20 VIDEO SPECIALIST: My name is Michael
21 Gay. I am with Golkow Technologies. Our court
22 reporter today is Linda Kinkade, also with Golkow
23 Technologies, and will now swear in our witness.

24

1 NICOLETTE S. HORBACH, M.D.,
2 Having been first duly sworn, was

3 thereafter examined and testified as follows:

4 VIDEO SPECIALIST: You may proceed.

5 EXAMINATION

6 BY MR. SLATER:

7 Q. Good morning, Dr. Horbach.

8 A. Good morning.

9 Q. I introduced myself a moment ago. My
10 name is Adam Slater. I'm going to take your
11 deposition now. You understand that's the
12 purpose of this proceeding, correct?

13 A. Yes.

14 Q. You understand you must tell the truth
15 in response to every single question I ask you
16 since you've now taken an oath to tell the truth?

17 A. Yes.

18 Q. If I ask you a question or anybody
19 asks you a question that doesn't make sense to
20 you for any reason, for example, I may
21 mispronounce a medical term or I may ask a
22 question that I think I understand a medical
23 process and I don't, if for some reason it
24 doesn't make sense to you, just tell me what's

1 unclear or what doesn't make sense, and I'll try
2 to refine the question so that it's something
3 that you feel you can answer truthfully,
4 accurately and completely. Okay?

5 A. Okay.

6 Q. The attorneys may object. I don't
7 expect there to be much speaking other than to
8 say "objection," and then you'll be told to go
9 ahead and answer. You don't need to be thrown
10 off by that; it just may occur from time to time.
11 Okay?

12 A. Okay.

13 Q. Have you ever been deposed before?

14 A. Yes.

15 Q. How many times?

16 A. I don't recall specifically, but
17 probably 10 or 12.

18 Q. And what were those depositions in
19 connection with?

20 A. Typically for medical-legal action
21 where I served as an expert or a treating
22 physician.

23 Q. I assume you've acted as an expert --
24 well, rephrase.

1 You've acted as an expert for defendants
2 in medical malpractice actions?

3 A. Yes.

4 Q. Have you acted as an expert for a
5 plaintiff in a medical malpractice action?

6 A. Yes.

7 Q. How many times?

8 A. I don't recall the specific number,
9 but probably of the cases I've reviewed somewhere
10 between 25 and 30% is plaintiff and the remainder
11 is defense.

12 Q. Of the depositions you've done, how
13 many have been for the plaintiff? You said 10 to
14 12 depositions.

15 A. I don't totally keep track. I know
16 that I've testified at least in several trials
17 for plaintiff, but I don't recall whether each of
18 those required depositions. Depending upon the
19 state, some do, some don't.

20 Q. Have you testified in court?

21 A. Yes.

22 Q. How many times?

23 A. Probably less than ten.

24 Q. Of the cases you've acted as an expert

1 in the past, you estimate about 25 to 30% has
2 been for the plaintiff and the other 70 to 75%
3 has been for the defense?

4 A. I'm sorry. Was that that I testified
5 in or that I've -- I meant that I've reviewed,
6 sort of being given medical records to review.
7 That's typically the balance. Not always does
8 that go on to either deposition or court.

9 Q. Okay. Good. Thank you for refining
10 that.

11 Once you get a file sent to you by
12 somebody, you look at it and say yes or no, I can
13 go forward as your expert, right, that's the
14 general process?

15 A. Typically, yes, or I give my
16 opinion --

17 Q. What --

18 A. Sorry.

19 Q. Of the cases where you have said, yes,
20 I'll go forward, what percentage is for the
21 plaintiff, what percentage is for the defense?

22 A. Probably 20, 25% plaintiff and the
23 rest defense.

24 Q. If you've given different percentages

1 under oath in the past, would you adhere to those
2 percentages you've given under oath in other
3 proceedings?

4 A. I think that's hard because things
5 continue to evolve from the last time I may have
6 given a deposition, and I don't keep a list of
7 all of the specific cases that I review. Once
8 they -- I've reviewed them, I toss them, and so,
9 as a result, I'm doing my best estimate of what I
10 can recall.

11 Q. When's the last time you testified for
12 a defendant in court as an expert?

13 A. For a defendant? It's been several
14 years.

15 Q. When's the last time you testified for
16 a plaintiff in court?

17 A. More recently. That was probably
18 within the last two or so years. My last
19 testimony in court was for a plaintiff.

20 Q. You hold yourself out as an expert in
21 the field of gynecology and urogynecology?

22 A. Yes.

23 Q. That is your expertise, correct?

24 A. Yes. I'm a board certified ob/gyn,

1 and I am trained as a urogynecologist and female
2 pelvic reconstructive surgeon.

3 Q. You do not hold yourself out as an
4 expert with regard to regulatory or FDA matters,
5 correct?

6 A. Correct.

7 Q. You do not hold yourself out as an
8 expert with regard to medical device industry
9 practices, meaning the internal practices of how
10 a medical device is developed, correct?

11 A. Correct.

12 Q. You have no expertise with regard to
13 design control or risk analysis, correct?

14 MS. JONES: I'm going to object to the
15 form of the question.

16 BY MR. SLATER:

17 Q. Let me ask you this. Do you know what
18 design control is?

19 A. I -- probably not in its manufacturing
20 definition, but I have an idea.

21 Q. Well, I'm not asking if you know what
22 the words "design control" means. My question
23 is, do you know what the term design control as
24 that term is used as a term of art in quality

1 engineering in the medical device industry means?

2 A. No.

3 Q. Okay. So you don't hold yourself out
4 as an expert with regard to design control,
5 correct?

6 A. Correct.

7 Q. Do you know the standards by which
8 Ethicon -- rephrase.

9 Do you know what standards Ethicon
10 believed it needed to meet with regard to the
11 labeling for the Prolift?

12 A. No, I don't know what Ethicon -- I
13 mean, I don't know what Ethicon was thinking or
14 believed that they needed to do. I wasn't there.

15 Q. And that would -- okay. I'm sorry.
16 When I say labeling, I'm talking about do you
17 know what Ethicon's internal standards were, what
18 they thought they had to do, in terms of -- well,
19 rephrase.

20 So you don't know what information Ethicon
21 internally believed they needed to include in the
22 IFU, the patient brochure, marketing documents,
23 all that sort of thing, that's not something
24 you're aware of, what standards they felt they

1 had to meet, correct?

2 A. Not within their internal standards,
3 just from the standpoint as a physician.

4 Q. So you don't know what standards
5 Ethicon Medical Affairs, Regulatory Affairs, what
6 those areas within the company felt they needed
7 to accomplish in putting information in the IFU,
8 the patient brochure, marketing documents, all
9 that sort of thing, correct?

10 A. Well, to some extent, but obviously
11 any of the documents that they were doing had to
12 meet regulatory approval through the FDA. I
13 mean, you can't start publishing issues or
14 putting information down that has not necessarily
15 received regulatory approval at least in portions
16 of it. Depends on how much they do through the
17 510(k).

18 Q. You think that the IFU and the patient
19 brochure that were reviewed and relied on by
20 Connie Schubert and Dr. Roberts were approved by
21 the FDA before they reviewed them?

22 A. Those were not because the FDA did not
23 look at the information until after, I think, it
24 was 2008 or later at the time that they were

1 reviewing the documents for Prolift+M.

2 Q. Let me come back to my question. You
3 do not know what standards Ethicon Medical
4 Affairs and Regulatory Affairs believed applied
5 to what information had to be included in the
6 IFU, the patient brochure, marketing materials,
7 you don't know what those standards were that the
8 company believed it had to adhere to; is that a
9 true statement?

10 MS. JONES: Object to the form.

11 THE WITNESS: Okay. Yes, I think
12 that's a true statement. I wasn't there at the
13 time.

14 BY MR. SLATER:

15 Q. Okay. And from the materials you've
16 reviewed, you don't know what those standards
17 are, correct?

18 A. I've looked at some of the internal
19 documents from the standpoint of emails,
20 et cetera, but I have not seen anything that
21 specifically addresses what has -- what they felt
22 had to be in the IFU or the patient brochure.

23 Q. Since you don't know what standards
24 Ethicon felt it had to meet, you won't be

1 offering any opinion as to whether or not Ethicon
2 met those standards because, if you don't know
3 what the standard is, you can't give an opinion
4 whether the standard was met, correct?

5 MS. JONES: Object to the form.

6 THE WITNESS: I disagree with that. I
7 disagree with that.

8 BY MR. SLATER:

9 Q. Well, let me ask you this. If you
10 don't know what -- if you don't know the standard
11 that Ethicon applied, you can't tell me whether
12 or not Ethicon met that standard or not as you
13 sit here right now, correct?

14 MS. JONES: Object to the form.

15 BY MR. SLATER:

16 Q. It's a yes-or-no question.

17 A. I think that from your type of
18 question that's probably correct, but I think
19 that the issue of the standard of what Ethicon
20 needs to be able to -- the medical standard that
21 Ethicon needed to be able to document for the IFU
22 or patient brochure, there is a medical standard
23 that needs to be adhered to as well, whether
24 that's an internal standard on the part of the

1 company or it's a more global standard that's
2 applied medically, since the standard that
3 Ethicon had may be different than what it is on a
4 global perspective.

5 Q. Well, the standard that you're
6 applying to your opinion as to whether or not the
7 IFU, for example, was adequate, that's your own
8 personal standard of what you think would need to
9 be in the IFU, correct?

10 A. It's a medical decision. It's a
11 medical determination on the part of my expertise
12 and my medical opinion, yes.

13 Q. As to whether or not Ethicon met its
14 own internal standards or the standards that
15 Ethicon thought it needed to meet because you
16 don't know what those standards are.

17 A. That's correct.

18 Q. Correct?

19 A. That's correct.

20 Q. Okay. You do not know -- rephrase.

21 Am I correct that you do not know what the
22 internal design standards were that Ethicon was
23 following in determining whether or not to market
24 the Prolift?

1 MS. JONES: I'm sorry. What was the
2 last part of that question?

3 BY MR. SLATER:

4 Q. I'll ask it again. Am I correct that
5 you do not know what the internal Ethicon
6 standards were that they were following to
7 determine whether or not the Prolift should be
8 marketed or not?

9 A. I'm not sure. If you could specify
10 more by "standards."

11 Q. Are you aware of any standards that
12 existed within Ethicon that people within Ethicon
13 had to follow in order to determine whether or
14 not they could market the Prolift?

15 A. That were rules within Ethicon itself?
16 No, I'm not aware of them.

17 Q. Yes. Okay. You don't know those
18 standards --

19 A. I don't know what the rules are within
20 Ethicon that allowed themselves to market or not
21 market the product.

22 Q. Since you don't know those rules, you
23 obviously won't be offering an opinion as to
24 whether or not those rules or standards were met,

1 correct?

2 A. Not within -- whether or not the
3 standards within the company were met by the
4 company, no, I would not be --

5 THE REPORTER: Wait a minute, counsel.
6 We need to finish the answer before the next
7 question.

8 BY MR. SLATER:

9 Q. I apologize. There's a delay. I'll
10 be more patient.

11 THE REPORTER: Thank you.

12 MR. SLATER: Could you read me her
13 answer, please, because I think I did -- I
14 apologize. I'll try to not do that again.

15 (The record was read by the reporter.)

16 BY MR. SLATER:

17 Q. Were you going to finish saying you
18 would not be offering an opinion on that subject?

19 A. Correct. I would not be offering an
20 opinion on whether or not Ethicon met its own
21 internal standards and rules before it marketed
22 the product.

23 Q. Have you ever been paid money by
24 Ethicon other than as a legal expert in this

1 litigation?

2 A. In this litigation, no, I have not
3 been paid money by Ethicon period yet.

4 Q. Okay. Other than acting as a
5 litigation expert with regard to this litigation,
6 have you ever been -- well, let me ask this
7 question. Have you ever been a preceptor or a
8 proctor for any Ethicon medical device?

9 A. No.

10 Q. Have you ever been a preceptor or a
11 proctor for any device or drug that was marketed
12 by any Johnson & Johnson company?

13 A. No.

14 Q. Have you ever participated in any
15 meetings sponsored by or run by Ethicon with
16 regard to any Ethicon device or product?

17 A. In 2001 I participated in a focus
18 group with myself and a number of other
19 physicians within the urogynecologic community
20 that was apparently an Ethicon-based meeting
21 asking our opinions regarding different products.

22 Q. When you gave your opinions and your
23 thoughts on that, did you tell what you actually
24 thought?

1 A. Yes.

2 Q. Have you reviewed the document that
3 documents that meeting?

4 A. Not the entire document, only a brief
5 statement of, you know, that I was more of a
6 skeptic and looking at getting more information.

7 Q. That brief statement was found in the
8 document?

9 A. Yes, in the document that I saw. I
10 mean, I personally had totally forgotten that I
11 had ever done the meeting since it was in 2001,
12 but it was brought to my attention by the Ethicon
13 attorneys.

14 Q. Here's my question. Did you actually
15 review the document itself or did you just get a
16 summary of what was in the document?

17 A. No, I saw the piece of paper that made
18 the statement that had my name on it. I did not
19 see the entire minutes of the meeting, if there
20 were any.

21 Q. So other than the part of -- so other
22 than the part of the document that indicated you
23 were a skeptic, you didn't look at any of the
24 other statements that were attributed to you in

1 the document?

2 A. I don't know whether any other
3 statements were attributed to me. I don't know
4 what the -- what the rest of the minutes or what
5 other statements were in there, in that document.

6 Q. Can you describe to me your medical
7 practice?

8 A. My current medical practice, I am in a
9 group of four other fellowship-trained
10 urogynecologists and reconstructive surgeons.
11 I'm the senior partner. My practice is primarily
12 based out of Fairfax, Virginia where our primary
13 office is. I do operate primarily at INOVA
14 Fairfax Hospital, although I do have privileges
15 and operate periodically at a hospital in
16 Montgomery County at Shady Grove Adventist
17 Hospital.

18 My practice is almost exclusively
19 urogynecology and pelvic reconstructive surgery.
20 I have a very small number of patients that I
21 currently see as general gynecology, individuals
22 that I've been taking care of for long periods of
23 time.

24 Within urogynecology my focus is areas of

1 incontinence, pelvic organ prolapse, urinary
2 tract infections, pain issues, pelvic muscle
3 dysfunction. I also deal with patients who have
4 had complications associated with prior
5 surgeries. We are a referral group, and so I see
6 a fair number of patients who were sent to me
7 with complications from other surgeries with or
8 without mesh, with or without incontinence versus
9 prolapse surgeries. And then will oftentimes be
10 the person involved with managing that patient
11 postoperatively.

12 Q. Pelvic muscle dysfunction, you're
13 talking about pelvic-floor myalgia?

14 A. Well, we use the term a little more
15 specifically that the patient has either pain
16 associated or dysfunction associated with
17 abnormalities of the pelvic muscles usually due
18 to increased tone causing increased tenderness in
19 the area, that then causing pain, which can then
20 also create other functional symptoms.

21 Q. The definition you just gave me would
22 be your definition of pelvic muscle dysfunction?

23 A. That's what we will use commonly to be
24 the clinical definition within our practice.

1 There is not really a --

2 Q. So pelvic --

3 MS. JONES: I don't think she was
4 finished, Adam.

5 THE WITNESS: That's okay. I'll stop.

6 MS. JONES: Okay.

7 BY MR. SLATER:

8 Q. Pelvic-floor myalgia would fall within
9 the overall context of pelvic muscle
10 dysfunction --

11 A. Yes.

12 Q. -- by your definition?

13 A. Yes.

14 Q. How did you get contacted to act as a
15 litigation expert for Ethicon with regard to the
16 Prolift?

17 A. I was contacted by an attorney
18 approximately a year and a half ago or so -- I
19 think it was early 2012 -- and was asked if I
20 would be willing to review a medical record for a
21 patient who was -- had filed a claim against
22 Ethicon.

23 Q. Why did you agree to do it?

24 A. Well, I agreed to review it. I agreed

1 to review the record. Why? I think --

2 Q. Yes.

3 A. I'm sorry. We lost your auditory.

4 Q. Sure. My question is this: Why did
5 you agree to review the medical record of
6 somebody who was suing Ethicon? Why did you
7 agree to do that for Ethicon?

8 A. Because I had had experience with the
9 product and I had actually believed that the
10 product was a good product and was something that
11 I had used in my practice. So I was willing to
12 at least look at the record and determine whether
13 or not I felt that there was evidence that I
14 could support or not relative to the care of this
15 particular patient.

16 Q. Who was the patient?

17 THE WITNESS: Am I allowed to give
18 that from confidentiality standpoints? I'm
19 sorry. I just lost his auditory.

20 BY MR. SLATER:

21 Q. Who was the patient?

22 MS. JONES: Let me just get one
23 issue -- let me talk with Dr. Horbach one second.

24 I think you can answer the question, but

1 let me just go off the record one second.

2 VIDEO SPECIALIST: The time now is

3 10:44. We are going off the record.

4 (Proceedings recessed.)

5 VIDEO SPECIALIST: The time now is

6 10:45. We are back on the record.

7 THE WITNESS: Can you repeat -- would

8 you repeat the question, please?

9 BY MR. SLATER:

10 Q. Who was the patient?

11 A. The initial patient that I was asked
12 to review was Pamela Wicker.

13 Q. Pam Wicker was the first record that
14 you reviewed on behalf of Ethicon regarding the
15 Prolift litigation?

16 A. Yes.

17 Q. Do you intend to act as an expert with
18 regard to Ethicon stress urinary incontinence
19 devices?

20 A. I don't know. I haven't been
21 specifically asked to review a -- anything
22 related to a case for stress incontinence
23 devices. I've been primarily involved with this
24 case, Ms. Schubert, as well as Ms. Wicker.

1 Q. You would agree with me that the
2 overall -- rephrase.

3 You would agree with me that the
4 overwhelming majority of your publications
5 address stress urinary incontinence, correct?

6 A. They may or may not, yes. I don't
7 recall.

8 Q. You don't know the fact that with the
9 exception of maybe two or three publications
10 every other one addresses stress urinary
11 incontinence?

12 A. My practice and my expertise --

13 Q. One second. I want to get one ground
14 rule straight. If I ask you a direct question
15 about a specific subject, I just ask you to
16 answer it.

17 I didn't ask you about your practice. I
18 didn't ask you about your background. I asked
19 about your publications and the fact that the
20 overwhelming majority is stress urinary
21 incontinence other than a couple of articles,
22 maybe two or three; is that a true statement?

23 A. I was trying to answer your question
24 originally. My answer was I don't know because I

1 haven't looked at my CV and those publications
2 recently. And because I do not publish on a
3 regular basis, I haven't counted how many
4 articles I've done relative to stress
5 incontinence versus pelvic organ prolapse. And I
6 was prefacing that statement by saying that the
7 type of practice and my expertise is not
8 necessarily in the research area; it's more in
9 clinical practice as well as educational
10 guidelines in the field and my participation
11 nationally.

12 Q. Do you hold yourself out as an expert
13 with regard to clinical study design?

14 A. As clinical study design itself, no.

15 Q. -- on a regular basis, correct?

16 A. What was --

17 MS. JONES: Adam, you got cut off.

18 THE WITNESS: What was the regular
19 basis?

20 BY MR. SLATER:

21 Q. You do not publish in the medical
22 literature on a regular basis, correct?

23 A. I don't know what you mean by "regular
24 basis."

1 Q. Doctor, I'm taking exactly what you
2 just said to me as part of your answer before.
3 You said you do not publish on a regular basis.
4 So what I did was I pulled that out and asked it
5 as a discrete question. So I'll ask the question
6 again.

7 Am I correct that you do not publish in
8 the medical literature on a regular basis?

9 A. I don't know whether your definition
10 of regular basis is the same as mine, but I do
11 not publish -- I do not publish in the medical
12 literature on a yearly or more than yearly basis,
13 no, not typically.

14 Q. And that's been true throughout your
15 career, correct?

16 A. Yes. My focus has been more in
17 teaching rather than in original research.

18 Q. In your medical practice have you had
19 patients that you placed a Prolift into and they
20 had complications?

21 A. I don't know what you mean by
22 "complications." You need to be more specific.

23 Q. What it means --

24 A. I'm sorry. You're cutting out during

1 many of the questions.

2 Q. Do you know what the word

3 "complications" means?

4 A. Yes.

5 Q. Have you had patients that you placed
6 a Prolift into who had complications as a result?

7 A. Yes.

8 Q. How many Prolifts would you say you've
9 placed?

10 A. Probably between a hundred and two
11 hundred.

12 Q. How many Prolift+Ms have you placed?

13 A. Not very many.

14 Q. Why not?

15 A. I just never transitioned to it. I
16 didn't feel a need to.

17 Q. Can you estimate the number of
18 Prolift+M medical devices you've placed in women?

19 A. I said not very many. I can't
20 estimate better than that.

21 Q. Could you give me a more specific
22 estimate? "Not very many," are you talking about
23 less than ten?

24 A. I can't answer that.

1 Q. Are you talking about less than 20?

2 A. I said, I can't answer that. I don't
3 know.

4 Q. Could it be as few as one or two?

5 A. It's possible.

6 Q. Could it be that you've never used a
7 Prolift+M?

8 A. No.

9 Q. So you think you've used it in maybe
10 as few as one or two times?

11 A. It's possible. I don't keep -- I
12 mean, you know, I don't keep track of every
13 particular procedure I do, but I use -- the bulk
14 of my surgeries were with the standard Prolift.

15 Q. Did you prepare for this deposition?

16 A. Yes.

17 Q. How much time did you spend preparing?

18 A. Are you saying for the entire review
19 of this particular record or are you saying just
20 for this deposition here?

21 Q. Just for the deposition.

22 A. Probably between 30 and 40 hours.

23 Q. Prior to your preparation for the
24 deposition how much time had you spent working on

1 this litigation?

2 A. On this particular patient?

3 Q. -- of documents and information and
4 this patient's records as well.

5 A. I'm sorry. You cut out through the
6 first part of the question.

7 MS. JONES: Adam? Adam, I don't
8 know -- I'm not sure what it is, but we're not
9 getting the first three or four words of your
10 questions sometimes, so just -- you may want to
11 put the speaker closer to you.

12 MR. SLATER: If it happens -- it's
13 right in front of me, so it's not that. If it
14 happens, just tell me and I'll have to repeat it.
15 Technology is not perfect. We'll do the best we
16 can.

17 BY MR. SLATER:

18 Q. How much time overall have you spent
19 with regard to the ProLift litigation and the
20 review of Connie Schubert's medical records aside
21 from the deposition prep that you just told me
22 was 30 to 40 hours?

23 A. And aside from my involvement with the
24 Wicker case?

1 Q. Aside from the time you spent specific
2 to Pam Wicker's medical records.

3 A. It's probably between 75 and a hundred
4 or so hours.

5 Q. How much time did you spend looking at
6 just Pam Wicker's medical records?

7 A. A lot. I don't recall off the top of
8 my head. She had a very extensive medical
9 record.

10 Q. More than 50 hours?

11 A. I don't think so, but I'm not sure.

12 Q. Have you invoiced Ethicon for the time
13 you've spent working as an expert for them in the
14 mesh litigation?

15 A. No.

16 Q. Do you have a record of how much time
17 you've spent?

18 A. Loosely.

19 Q. What are you billing for your time in
20 this litigation, what amount?

21 A. Five hundred dollars per hour.

22 Q. Is that for everything you do?

23 A. I charge \$500 per hour for review of
24 records and/or, you know, preparation. I charge

1 for either depositions or trial based on half
2 days out of my office. So at \$2,500 for a half
3 day out of my office.

4 Q. If you're going to be a full day like
5 today, you would charge \$5,000 for today's
6 deposition?

7 A. Yes.

8 Q. Is that what you're going to charge
9 when you go to Missouri to testify in this trial,
10 \$2,500 for a half day or \$5,000 for a full day?

11 A. Yes.

12 Q. Will you also be traveling -- well,
13 rephrase.

14 You will also charge for your time
15 traveling and preparing for the trial as well,
16 right?

17 A. Preparing for the trial. I don't
18 always necessarily charge for my travel time. If
19 I'm doing something else during the time that I'm
20 traveling that's not related to the litigation, I
21 don't typically charge.

22 Q. Out of the one hundred to two hundred
23 Prolifts that you have put in -- rephrase. Let
24 me just ask the question.

1 The best estimate you can give me for the
2 number of Prolifts that you have surgically
3 implanted in women is one hundred to two hundred?

4 A. That is the best estimate. I
5 attempted to get a better estimate by asking my
6 office to be able to pull information; however,
7 we've just gone through a practice reorganization
8 and a practice split, so they had difficulty
9 being able to retrieve the exact number for me.

10 Q. Of the one hundred to two hundred
11 Prolifts that you've placed, can you estimate the
12 percentage of those that would be total Prolifts?

13 A. I would expect that at least half
14 probably would be total Prolifts.

15 Q. You were trained on the Prolift by
16 Vincent Lucente, correct?

17 A. Yes.

18 Q. Do you know why the Prolift and
19 Prolift+M were pulled off the market?

20 MS. JONES: Object to the form.

21 THE WITNESS: I have an
22 understanding --

23 BY MR. SLATER:

24 Q. What, Doctor? I have to ask the

1 question again. Do you know why it is that
2 Ethicon stopped marketing the Prolift and the
3 Prolift+M?

4 A. It was my understanding from talking
5 with Ethicon that they felt the ability to
6 continue marketing the product in the face of
7 current litigation was something that was not
8 going to be a beneficial decision for the part of
9 the company, and that although they believe
10 strongly in the product and use of it in patients
11 as an alternative, that it was something that
12 they elected to do based on corporate decisions
13 or I don't know whether it was strictly
14 financially based or whether it was based on
15 medical-legal issues per se.

16 Q. You said in the start of your answer
17 they stopped marketing due to the current
18 litigation. That was your understanding?

19 A. It was current litigation sort of
20 climate more than in this specific litigation
21 itself, but the current litigation climate and
22 the current negative viewpoint for mesh.

23 Q. When you say "the current negative
24 viewpoint for mesh," you're talking about within

1 the medical and patient communities?

2 A. Yes.

3 Q. When's the last time you put a Prolift
4 into a woman's body?

5 A. It probably was -- it may have been
6 2011-ish or so. I don't really recall off the
7 top of my head.

8 Q. During the period of time when you
9 were using the Prolift were you also performing
10 alternative procedures to treat pelvic organ
11 prolapse?

12 A. Yes.

13 Q. You felt that there were certain
14 patients who were appropriate candidates for the
15 Prolift and you thought there were certain
16 patients who were not appropriate candidates,
17 correct?

18 A. Yes.

19 Q. And what was your criteria for
20 somebody to be an appropriate patient for the
21 Prolift?

22 A. The first criteria is that the patient
23 had symptomatic prolapse as defined by both
24 having symptoms as well as having sufficient

1 anatomic abnormalities to be able to explain the
2 degree of symptoms that the patient was
3 experiencing.

4 In addition, I would choose at times for
5 patients who were interested in uterine
6 preservation as being able to do a total Prolift,
7 typically allowed me to preserve the uterus,
8 where if I were doing something like a
9 sacrocolpopexy, I would usually recommend at
10 least a supracervical hysterectomy.

11 I would choose it at times in patients
12 where they had had a significant number of other
13 abdominal surgeries, and, therefore, entry into
14 the abdomen would not be preferable. I would
15 choose it in women who perhaps were more -- had
16 anesthetic issues or anesthetic risks such that a
17 full general anesthesia as required in a
18 sacrocolpopexy may not be optimal for them, and,
19 therefore, I could do a Prolift under perhaps
20 regional type of anesthesia and IV sedation.

21 I would choose it in patients where the
22 issue was relative to recuperation as the
23 alternative apical procedure that I was primarily
24 performing at that time was an open

1 sacrocolpopexy, and that was going to require the
2 patient to have a longer hospitalization as well
3 as longer restrictions and longer time to
4 recovery.

5 I'll follow up that statement. But in
6 reality, you know, my choice of doing a Prolift
7 is very much tied hand in hand with my counseling
8 of the patient. And so it becomes a mutual
9 decision between myself and my patient whether
10 it's a Prolift or any other type of surgery I do,
11 as I discuss with them the pros and cons of the
12 different surgical approaches.

13 Q. Over the last eight years can you
14 estimate for me the number of prolapse repair
15 procedures that you perform on an annual basis?

16 A. We have -- we have tracked the number
17 of prolapse procedures that we perform as a group
18 with the four of us. We haven't necessarily
19 specifically separated them out, although myself
20 and one of my other partners are the busiest
21 surgically.

22 We tend to perform -- I'm trying to
23 remember -- it's in the -- it's multiple
24 hundreds, but I would be -- I would be remiss in

1 giving a specific. I know that, when we have
2 looked at our volumes in our practice over the
3 years compared to other centers, such as the
4 Cleveland Clinic, that we do similar type of
5 volume as there is at Cleveland Clinic.

6 Q. -- of prolapse procedures you have
7 been performing over the last seven or eight
8 years on an annual basis?

9 A. I'm sorry. You have to start the
10 question again since it was lost.

11 Q. What is your best estimate of the
12 number of prolapse repair procedures you have
13 performed on an annual basis over the past seven
14 or eight years?

15 A. I would say probably between a hundred
16 and two hundred procedures, but I think it would
17 be difficult for me to give you anything more
18 specific than that.

19 Q. So your best estimate is that on an
20 annual basis over the last seven or eight years
21 you've been performing one hundred to two hundred
22 prolapse repair procedures per year?

23 A. That's my best estimate.

24 Q. Besides the Prolift, over the last

1 seven or eight years have you been using any
2 other mesh devices or materials for the treatment
3 of prolapse?

4 A. I've used other materials, no other
5 specific mesh kits, if you want to say mesh kits
6 per se, I've not used any other companies.

7 Q. What material or what mesh brands have
8 you used for your abdominal sacrocolpopexy?

9 A. I've used a number over the past
10 years. Most commonly it's been either Gynemesh
11 or more recently perhaps even Restoril for the
12 sacrocolpopexies. There was a period of time --
13 and I don't remember whether it was, you know,
14 prior to eight years ago or not -- where we used
15 standard Prolene meshes. We have probably at
16 some point in time more than eight years ago
17 would have been things like Marlex or Mersilene.

18 Q. From the time that the Prolift came
19 out, which was March of 2005, if you were going
20 to use mesh through the vagina to treat prolapse,
21 did you use the Prolift exclusively or did you
22 also at times take mesh and cut it and
23 incorporate it into a transvaginal repair?

24 A. No, I would use the Prolift

1 exclusively.

2 Q. So once the Prolift came on the
3 market, if you were going to use a vaginal --
4 rephrase.

5 So from the time the Prolift came on the
6 market, if you were going to perform a procedure
7 through the vagina to treat prolapse, you used
8 the Prolift, correct?

9 A. Yes. To the best of my recollection,
10 yes.

11 Q. And then sometime in to your best
12 estimate 2011 you stopped using the Prolift,
13 correct?

14 A. I stopped using it somewhere around
15 that time in part because we began using -- doing
16 laparoscopic sacrocolpopexies rather than open
17 procedures. And so the advantages of
18 laparoscopic sacrocolpopexies versus Prolift in
19 terms of recuperation, things became more
20 neutral, and so oftentimes we would go to
21 sacrocolpopexy.

22 Q. There came a point somewhere in 2011
23 to the best of your recollection when you
24 determined that, when you weighed the risks and

1 benefits for most of your patients, laparoscopic
2 abdominal sacrocolpopexy was a better procedure
3 than the Prolift for your patients in most cases,
4 correct?

5 A. In --

6 MS. JONES: Object to the form.

7 THE WITNESS: Does that mean I -- you
8 have -- does that mean you have to change -- say
9 it again or --

10 BY MR. SLATER:

11 Q. You can answer.

12 A. Okay. I think that I -- in weighing
13 the pros and cons -- I did decide that -- with
14 the patient -- that a laparoscopic sacrocolpopexy
15 may be more appropriate for that individual
16 patient.

17 Q. In around 2011 that conclusion was
18 reached with most of your patients and you
19 stopped using the Prolift, correct?

20 A. Yeah, to the best of my recollection
21 that was the time period.

22 Q. In your treatment of women with the
23 Prolift you had some patients who developed
24 complications due to the Prolift, correct?

1 A. Yes.

2 Q. The complications you saw included
3 mess erosion and mess exposure into the vagina,
4 correct?

5 A. No.

6 Q. You never had an exposure of any of
7 your patients with the Prolift?

8 A. No. That's correct. Not to my
9 knowledge.

10 Q. One of the things you realize is that
11 when women have complications following a surgery
12 like the Prolift, it's actually likely that they
13 are going to leave the doctor who did the surgery
14 and go to somebody else without telling the first
15 doctor what happened, correct?

16 MS. JONES: Object to the form.

17 THE WITNESS: That is correct, except
18 I think in this situation it is a little bit
19 different than it might be out in the generalized
20 community. Part of the issue is that there are
21 very few groups that do the more specialized
22 urogynecologic procedures. So we are typically
23 the -- one of the centers of last resort.

24 In addition, the two other centers that

1 might see the patients, we typically, among the
2 three of us, will send letters to each other
3 about having seen one of -- one of the other's
4 patients, whether it's second opinion, whether
5 it's a complication, so that there is that
6 communication that goes on back and forth.

7 In addition, if -- you have a frown. You
8 don't understand that?

9 Q. I understand. I'm just listening.

10 A. Okay. And the third issue is that
11 typically patients who will choose to go to
12 another physician for care will usually request
13 records of their surgery so that they can -- the
14 more current treating physician will be able to
15 know what was done, and that has not been
16 something that's happened in this -- in the cases
17 of my patients.

18 Q. If you had patients who suffered
19 complications, went to another doctor and told
20 that doctor, I don't want you in contact with
21 Dr. Horbach, I want to be treated by you now, I'm
22 unhappy how that Prolift went, you'd have no way
23 to know that, right?

24 A. That's correct.

1 Q. Have you treated women who had
2 Prolifts placed by other doctors and then came to
3 you suffering from complications?

4 A. Yes.

5 Q. How many times?

6 A. I don't recall.

7 Q. Can you give me an estimate? Is it
8 more or less than ten?

9 A. Yes.

10 Q. Which one?

11 A. I'm sorry. More.

12 Q. More than 20?

13 A. I don't know. When patients come to
14 see us, they will at times have had complications
15 associated to the insertion of mesh. I typically
16 have not kept track of whether that mesh was a
17 Pinnacle, an Apogee, a Perigee, a Prolift or a
18 free-formed mesh.

19 Q. The complications you've seen
20 regardless of whether it's a Prolift or these
21 other devices are similar, correct?

22 A. Are similar to what? To each other?

23 Q. One another, yes.

24 A. Yeah, that's typical.

1 Q. Your partner is Dr. Welgoss or
2 Welgoss?

3 A. He is one of my partners, yes.

4 Q. How do you pronounce his last name? I
5 just don't want to mispronounce it the whole
6 deposition.

7 A. Welgoss.

8 Q. Welgoss. You're familiar with the
9 fact that Dr. Welgoss has consulted with Ethicon
10 for many years, correct?

11 A. No.

12 Q. Didn't know that until right now?

13 A. I mean, I -- we don't keep track of
14 what each other does on an individual -- on our
15 own individual time. Typically I know that he's
16 worked as a preceptor for InterStim implants with
17 Mentor, but I wasn't aware of his specific
18 consultant work with Ethicon.

19 Q. So as of right now you're not aware
20 that Dr. Welgoss has consulted with Ethicon?

21 A. I can't say I -- I am aware that he
22 might have at some point had some interaction
23 with Ethicon similar to what I had back in 2001,
24 but when you said am I aware that he has

1 consulted for Ethicon on a regular basis, no, I
2 was not aware of that.

3 Q. In terms of patient-selection criteria
4 with the Prolift, do you believe that the
5 patient-selection criteria set forth in Committee
6 Opinion 513 should be applicable to the Prolift?

7 A. You're talking about from the
8 standpoint of the ACOG committee opinion?

9 Q. The ACOG/AUGS Committee Opinion 513,
10 do you believe that patient-selection criteria
11 that is stated in that committee opinion should
12 be applicable to the Prolift?

13 A. For me to accurately answer that, I'd
14 have to pull it. So if you give me a second,
15 I'll pull it out.

16 Q. Let me just ask you this. I'm not
17 asking you to pull it out. Are you familiar with
18 what Committee Opinion 513 says with regard to
19 patient-selection criteria?

20 A. I'm familiar with the bulk of it, but
21 if you're -- I can't tell you exactly each thing
22 that they list on the list.

23 Q. You read that committee opinion when
24 it came out, correct?

1 A. Yes.

2 Q. And when it came out, did you believe
3 it was a reasonable committee opinion and that
4 the conclusions were reasonable?

5 A. I think that they, at least from my
6 experience, that they overstated the problem, at
7 least from what we had seen.

8 Q. When you say what we have seen, you
9 mean within your own practice?

10 A. Correct.

11 Q. You're aware of the fact that your
12 practice is likely not representative of the
13 outcomes that would be obtained by physicians in
14 community medical practices throughout the
15 country, correct?

16 MS. JONES: Object to the form.

17 THE WITNESS: Yes, I'm aware that our
18 outcomes are probably not the same.

19 BY MR. SLATER:

20 Q. Your outcomes are likely much better
21 than what you would see across the board for
22 community physicians, correct?

23 A. I would hope so, but yes.

24 Q. I mean, you're a group of

1 fellowship-trained surgeons working out of
2 well-known hospitals with high levels of training
3 that would be beyond what you would expect most
4 physicians would have, correct?

5 A. Again, that's -- that would be
6 difficult for me to say. There are gynecologists
7 who are not fellowship trained, gynecologists who
8 still have a significant level of clinical skill
9 and experience in doing prolapse surgery.

10 Q. I'm generalizing.

11 A. Again, I would expect so, but I don't
12 think that it necessarily can be a global
13 generalization.

14 Q. Would you agree that my statement is
15 generally accurate although there may be
16 exceptions?

17 A. I think that's a reasonable statement,
18 yes.

19 Q. You do not hold yourself out as an
20 expert with regard to the material science issues
21 with regard to the various meshes that have been
22 used for prolapse repair, correct?

23 A. I -- before I answer that question,
24 I'd like to take a break for a second, please.

1 Can we go off the record?

2 Q. Not for a discussion with counsel,
3 right?

4 A. Yes.

5 Q. I'm correct?

6 A. I'm sorry. I missed the first part of
7 that question.

8 Q. You need to answer my question. We're
9 not going to take a break with a question
10 pending. So you need to answer that question,
11 please.

12 A. I can't answer that question, then.

13 Q. Okay. You can't answer it?

14 A. You wanted a yes or no, and that's why
15 I said I can't answer that without discussion
16 further.

17 Q. Well, you can't speak to counsel and
18 ask counsel how you should answer a question. So
19 I need to go through this with you. You can't go
20 to counsel and get advice on how to answer my
21 questions because your only guidance is to be to
22 answer me truthfully.

23 So you're unable to tell me whether or not
24 you hold yourself out as an expert with regard to

1 the material science of the meshes used for
2 prolapse repair, correct?

3 A. Correct, that's -- then to the best of
4 my ability, that's my statement.

5 Q. -- internal Ethicon documents with
6 regard to the understanding of the internal
7 Ethicon scientists as to the key material science
8 issues with the Prolift and Prolift+M, correct?

9 A. The beginning of your question was
10 lost, but did you say did I review them? Did I
11 review documents?

12 Q. Here's my question. Did you review
13 the internal documents from Ethicon that set
14 forth what the scientists and medical affairs
15 people in Ethicon thought were the key issues
16 with regard to the mesh used in the Prolift?

17 A. I reviewed some of the basic science
18 work that was done through Ethicon relative to
19 the animal studies associated with different
20 meshes, yes. I don't know whether that's every
21 single document.

22 Q. That's what you looked at, with regard
23 to material science internally at Ethicon, you
24 looked at the preclinical studies with animals

1 that you listed on your reliance materials,
2 correct?

3 A. Yes, that's primarily it.

4 Q. Well, is there anything else? Right
5 now I just need to know. That's what you looked
6 at, right?

7 A. I believe so.

8 Can I take a break now, please?

9 Q. Sure.

10 A. Thank you.

11 VIDEO SPECIALIST: The time now is
12 11:16. We are going off the record.

13 (Proceedings recessed.)

14 VIDEO SPECIALIST: The time now is
15 11:28. We are back on the record.

16 MR. SLATER: Sara, do you have the
17 exhibit, the committee opinion --

18 THE WITNESS: I actually just had
19 pulled out the committee opinion, although I
20 think my copy was my own and does not have an
21 exhibit.

22 BY MR. SLATER:

23 Q. We have a marked one from another
24 litigation. Let's use that one.

1 A. So does somebody have that? I'd be
2 happy to look at it.

3 MS. JONES: Adam, what your assistant
4 here has handed me is marked Plaintiff's Exhibit
5 number 125.

6 MR. SLATER: That's the document,
7 Committee Opinion 513.

8 MS. JONES: Okay. December 2011. All
9 right. And do you want it separately --

10 MR. SLATER: It was marked in another
11 deposition in the consolidated litigation.

12 MS. JONES: All right. But we're not
13 part of the consolidated litigation, so do you
14 want this separately marked? That's my question.

15 MR. SLATER: No. No, I'm good.

16 MS. JONES: Okay. That's fine.

17 MR. SLATER: I don't think we'll ever
18 have a dispute about whether or not this is the
19 committee opinion or not.

20 MS. JONES: No, that's fine. I wanted
21 to make sure we were dealing with this as you
22 preferred.

23 MR. SLATER: No problem.

24 BY MR. SLATER:

1 Q. Okay. Doctor -- are we back on?

2 THE REPORTER: Yes, sir.

3 MS. JONES: We are.

4 BY MR. SLATER:

5 Q. Okay. Doctor, in front of you is
6 Committee Opinion 513. It actually has a sticker
7 or a copy of a sticker on the top right that says
8 Exhibit 125 from another deposition. Do you see
9 that?

10 A. Yes.

11 Q. You're familiar with this committee
12 opinion, correct?

13 A. Yes.

14 Q. Did you have any involvement in the
15 drafting of this committee opinion?

16 A. No.

17 Q. What I'd like to do is turn to the
18 recommendations at the very end, page 1463.

19 A. Okay.

20 Q. The second bullet point of the
21 recommendations says:

22

23 Pelvic organ prolapse, vaginal mesh
24 repair, should be reserved for

1 high-risk individuals in whom the
2 benefit of mesh placement may
3 justify the risk such as
4 individuals with recurrent prolapse
5 particularly of the anterior
6 compartment or with medical
7 comorbidities that preclude more
8 invasive and lengthier open and
9 endoscopic procedures.

10 Do you see that?

11 A. Yes.

12 Q. -- recommendation is reasonable,
13 correct?

14 A. I don't agree with it.

15 Q. Do you believe it's a reasonable
16 recommendation?

17 MS. JONES: Object to the form.

18 THE WITNESS: I think you need to be
19 more specific about reasonable. I think that it
20 is -- it is something that ACOG put together as
21 information to go out to the general ob/gyn
22 community. And sometimes, based on how ACOG
23 generates these types of documents, they create
24 sort of a narrower window where they are -- it's

1 less applicable to specialists who are doing this
2 type of surgical training or -- sorry -- it's
3 less applicable to specialists surgeons who are
4 doing prolapse work.

5 BY MR. SLATER:

6 Q. When you say a specialist, you're
7 talking about someone like yourself who is
8 fellowship-trained and does a very high volume of
9 this type of surgery?

10 A. Yes, that's one component, but I'm
11 also talking about there are general gynecologic
12 surgeons, people who are not specifically
13 fellowship-trained, but who are extremely skilled
14 reconstructive surgeons and who do do that as a
15 bulk of their practice. I don't think you have
16 to be specifically fellowship trained to be able
17 to do this type of surgery well.

18 Q. Would you agree with me that this
19 recommendation is reasonable for doctors who are
20 not the most highly skilled surgeons, as you've
21 described them, those who are either
22 fellowship-trained with high volume or those who
23 may not be fellowship-trained but still have a
24 high volume and have a very high level of skill?

1 MS. JONES: Object to the form.

2 THE WITNESS: I think that this is a
3 reasonable comment for someone who does not do
4 prolapse surgery as their primary focus of their
5 practice.

6 BY MR. SLATER:

7 Q. And with regard to that profile of
8 physician, this would be a reasonable
9 recommendation with regard to the Prolift or the
10 Prolift+M, correct?

11 A. Yes.

12 Q. Let's look through some of the
13 language in this document. If you could, turn to
14 page 1461. In the right-hand column the first
15 full paragraph it says:

16 Risk factors for developing intractable
17 pain after vaginal mesh placement are not
18 understood.

19 Is that a statement you agree with?

20 A. I think that there is some
21 understanding of some of the risk factors. I
22 don't think that there is an understanding about
23 all of the risk factors.

24 Q. A little further down right after

1 footnote 17 it says:

2 Hernia mesh also is known to undergo
3 retraction and pain persists in patients at five
4 years.

5 Do you see that?

6 A. Yes, I see that.

7 Q. Are you aware of the fact that, with
8 hernia mesh, there are patients who suffer
9 retraction of the mesh and chronic pain that can
10 be disabling for patients?

11 A. Yes.

12 Q. A little further down it talks about
13 the fact that mesh grafts in the vagina are
14 placed in a clean contaminated field with a
15 single vaginal incision and the arms --

16 A. Can you hold on? Okay. Thank you. I
17 found it. I'm sorry.

18 Q. I'll start over. In that first full
19 paragraph on the right column of page 1461 it
20 talks about the placement of mesh grafts in the
21 vagina being a clean contaminated field, and then
22 it says:

23 And the arms of some mesh
24 configurations pass into the

1 obturator internus and levator ani
2 muscles. Shrinkage or contraction
3 of mesh around these structures or
4 excess tension on the mesh arms can
5 cause vaginal pain in some
6 individuals.

7 Do you see where I just read?

8 A. Yes.

9 Q. Those are true statements, correct?

10 A. Yes.

11 Q. And that would apply to the Prolift
12 and Prolift+M, correct?

13 A. Yes.

14 Q. A little further down it talks about,
15 about three lines down:

16 The addition of synthetic mesh
17 could make the vagina a cylindrical
18 organ that expands and contracts
19 less pliable and perhaps more prone
20 to pain or dyspareunia.

21 That's a true statement, correct?

22 A. Yes.

23 Q. And that would apply to the Prolift
24 and Prolift+M, correct?

1 A. Yes.

2 Q. The next paragraph -- rephrase.

3 The second full paragraph in the right
4 column of page 1461 there is a statement about
5 four lines down that points to a small but
6 significant group of patients who experience
7 permanent and life-altering sequelae including
8 pain and dyspareunia from the use of vaginal
9 mesh. Do you see that?

10 A. Yes, I see that.

11 Q. And you would agree there is a
12 significant group of patients who experience
13 those -- that level of complication, correct?

14 A. I think that the term "significant" is
15 something that can be interpreted in different
16 ways, so I don't know that I could say
17 significant, but there is a portion -- there are
18 a portion of women who develop problems that can
19 have significant impacts or be life-altering.

20 Q. And that's true for the Prolift and
21 Prolift+M, correct?

22 A. Yes.

23 Q. Just a sentence -- rephrase.

24 Just in the middle of this second full

1 paragraph on page 1461, right column, it says,
2 large-scale registries are urgently needed. Do
3 you see that?

4 A. Yes.

5 Q. Do you know why Ethicon did not
6 utilize a registry for the Prolift?

7 A. No.

8 Q. If Ethicon decided not to have a
9 registry with regard to the Prolift because they
10 were afraid that this would create more accurate
11 information about the complications from the
12 Prolift and thus give more of an accurate view of
13 the entire complication profile and as compared
14 to devices sold by other manufacturers without
15 registries, from a marketing standpoint, the
16 Prolift would look worse. If that's the reason
17 Ethicon didn't have a registry, you would have a
18 serious problem with that, correct?

19 MS. JONES: Object to the form.

20 THE WITNESS: I don't know that I
21 could say that.

22 BY MR. SLATER:

23 Q. Let's go to the next page. Go to the
24 right-hand column. There is a long continuation

1 of a paragraph, and just above the first full
2 paragraph there is a phrase I want to ask you
3 about. Okay? It says:

4 The removal of mesh because of mesh
5 complications may involve multiple
6 surgical procedures and
7 significantly impair the patient's
8 quality of life. Complete removal
9 of mesh may not be possible and may
10 not result in complete resolution
11 of complications including pain.

12 That's a true statement with regard to the
13 Prolift and Prolift+M, correct?

14 A. Yes.

15 Q. Let's look at the -- right under the
16 summary in the right-hand column. It says:

17 Mesh kits for repair of prolapse
18 were first marketed to urologists
19 and gynecologists as a way to
20 improve success rates for prolapse
21 repairs with native tissue but
22 without well-designed trials to
23 establish the safety and efficacy
24 of these devices.

1 That's a true statement, correct?

2 MS. JONES: Object to the form.

3 THE WITNESS: The comment of

4 "well-designed," if you were to substitute

5 without randomized controlled trials, I would say

6 yes.

7 BY MR. SLATER:

8 Q. Randomized controlled trials are

9 considered the gold standard for clinical studies

10 in this field, correct?

11 A. Yes, any field.

12 Q. And that statement would be true for

13 the Prolift, that the Prolift was launched

14 without randomized controlled trials to establish

15 the safety and efficacy of the Prolift, correct?

16 A. Yes.

17 Q. In fact there was never a study done

18 of the Prolift as it was actually marketed before

19 it went on the market. Are you aware of that?

20 MS. JONES: Object to the form.

21 THE WITNESS: I want to clarify your

22 question, meaning there wasn't -- that the

23 studies that were there prelaunch were

24 specifically more the TVM studies and that the

1 actual kit itself wasn't involved in those
2 prelaunch studies. Is that -- I just want to
3 make sure that that's the question you're asking.

4 BY MR. SLATER:

5 Q. Right. There was never a study
6 performed by Ethicon of the Prolift as it was
7 marketed in the package. That system was never
8 studied before it went on the market, correct?

9 A. The package system that they sent,
10 yes, that's correct.

11 Q. Do you know how or to what extent
12 Ethicon Medical Affairs relied on the data from
13 the French and U.S. TVM studies before the launch
14 of the Prolift?

15 MS. JONES: Object to the form.

16 THE WITNESS: Relied for what?

17 BY MR. SLATER:

18 Q. In any way. Do you know how -- I'll
19 ask the question again.

20 Do you know how Ethicon Medical Affairs
21 relied on the data from the French and U.S. TVM
22 studies either before or after the launch of the
23 Prolift? Do you know how Ethicon Medical Affairs
24 used and relied on that data?

1 A. To do what? I'm still not -- I'm
2 sorry. I don't --

3 Q. For any reason, for any purpose. Do
4 you have any knowledge of how Ethicon Medical
5 Affairs used that data?

6 A. Probably --

7 Q. I'm not asking you to speculate or
8 guess.

9 A. No, no.

10 Q. I want to know based on -- let me
11 finish. I want to know based on something you
12 read in actual documents that were provided to
13 you.

14 A. That was why I paused to think about
15 whether or not I had read anything specifically
16 in a document. I do not recall reading anything
17 specifically in any of the Ethicon documents
18 regarding that issue.

19 Q. Same question with regard to the
20 Gynemesh PS study.

21 A. Of how the -- of how Ethicon relied on
22 that in its marketing or -- is that what you're
23 asking?

24 Q. For any reason. If you have knowledge

1 of how Ethicon relied on that data for any reason
2 at all from reading the internal documents to see
3 how they actually used or relied on that data.

4 A. I think --

5 MS. JONES: I'm going to object to the
6 form.

7 THE WITNESS: I think your question --
8 you have to rephrase the question, then, in that
9 case. It's hard for me to answer.

10 BY MR. SLATER:

11 Q. Okay.

12 A. I think that -- I do recall reading
13 information about internal communications among,
14 you know, Ethicon when they were talking about,
15 you know, the clinical report or issues that
16 were, you know, involved with gathering data, but
17 I'm not sure I can give you the specifics.

18 Q. Okay. This is my question. Do you
19 have any knowledge as you sit here right now from
20 the review of all the materials you were given as
21 to how or to what extent the people in the
22 Ethicon Medical Affairs actually used or relied
23 on the data from the Gynemesh PS study?

24 A. That question I can answer. No, I

1 don't.

2 Q. Okay. You did not review the actual
3 case report forms or data compilations or any of
4 the underlying data with regard to the Gynemesh
5 PS study, correct?

6 A. I reviewed -- not for the Gynemesh PS.
7 I had examples of the data collection form, I
8 think, for the TVM portion of the study.

9 Q. My question is limited to the Gynemesh
10 PS study. You have not looked at of the
11 underlying case report forms or underlying data
12 with regards to that study, correct?

13 A. No, I don't think so.

14 Q. Meaning I'm correct?

15 A. Yes. Yes, you're correct. Sorry.

16 Q. With regard to the French and U.S. TVM
17 studies, did you review any of the underlying
18 case report forms or data for that -- for those
19 studies?

20 A. I have seen an example of some of the
21 case report forms that I believe were part of the
22 TVM study in the United States.

23 Q. Was that just so you could see what
24 the forms look like and see what information was

1 generally found on them?

2 A. Yes.

3 Q. You did not do an analysis of the
4 underlying data for the French or U.S. TVM
5 studies, correct?

6 A. Correct.

7 Q. Would you agree with me that, when you
8 put yourself up as an expert witness in a case
9 like that, that it's important for you to give
10 objective testimony?

11 A. Yes.

12 Q. Would you agree with me that, when you
13 put yourself up as an expert in this case --
14 well, rephrase.

15 Would you agree with me that, when you put
16 yourself up as an expert in a case like this,
17 that you review the documents that provide the
18 information you would need to provide a
19 well-supported opinion?

20 A. Yes, I believe that -- if I followed
21 your train of questions -- yes, I would think
22 that that would be the case for any opinion that
23 I'm asked to render, yes.

24 Q. -- in offering opinions in a case like

1 this that you, as an expert, need to know the key
2 facts that would go into the issues that you're
3 giving opinions on?

4 A. Yes.

5 Q. Would you agree that you want to have
6 all of the necessary background information so
7 that when you give your opinions they are
8 supported by the actual facts of what existed and
9 what occurred?

10 A. Yes, I have either felt that I have
11 reviewed the information that was necessary or
12 have reviewed comments by other individuals who
13 have reviewed the information that's necessary to
14 render my opinion.

15 MR. SLATER: Could I have that read
16 back to me, please?

17 (The record was read by the reporter.)

18 BY MR. SLATER:

19 Q. When you say you've reviewed comments
20 by other individuals, who are you referring to?

21 A. The deposition of Dr. Anne Weber.

22 Q. -- Weber's deposition?

23 A. I'm sorry?

24 Q. -- deposition?

1 A. We're still -- you're still cutting
2 out for half of that.

3 Q. Oh, I'm sorry. Well, it's better than
4 me having to come to D.C., so...

5 Did you review Dr. Weber's deposition? Is
6 that what you're saying?

7 A. Yes, I did.

8 Q. Which deposition?

9 A. The deposition that was recently taken
10 regarding this particular case.

11 Q. Okay. Do you know the volume of
12 documents that were produced in this litigation?

13 A. I understand from Dr. Weber's
14 deposition that it was perhaps close to a million
15 or so documents that she has reviewed.

16 Q. -- overall volume of documents that
17 have been produced in the overall litigation
18 involving the Prolift and Prolift+M?

19 A. Again, I missed the first part, but do
20 I know what the total is? I don't know what the
21 total number of documents, but I know she said
22 she has reviewed close to a million documents.

23 Q. Ask anybody what the total volume of
24 documents is that has been produced in this

1 litigation regarding the Prolift or Prolift+M?

2 A. No.

3 Q. Did you ever ask anybody what has been
4 produced in the overall litigation so you could
5 have an understanding of what existed and then
6 you could ask to see the things you thought were
7 important to see?

8 A. I did not ask what has been produced
9 for the entire litigation.

10 Q. Did you make an effort to learn what
11 important documents existed -- and when I say
12 "important" -- documents that would be important
13 to being able to give a fully informed opinion on
14 the issues you wanted to address -- did you ever
15 make an effort to learn what documents and
16 information existed so you could then say, well,
17 I want to see this, I want to see that?

18 A. In this particular case I have
19 requested the information that I thought I needed
20 to make the opinions that I was making
21 clinically, yes.

22 Q. Clinically, you're talking about with
23 regard to Connie Schubert specifically?

24 A. Yes, that's what we're taking the

1 deposition about is Connie Schubert.

2 Q. Is it your understanding that your
3 role in this case is to talk solely with regard
4 to Connie Schubert?

5 A. Well, let me -- you missed the first
6 question. If your question is, is my role just
7 to talk about her, my role in this case, I've
8 been asked to be a clinical expert relative to
9 prolapse as a problem in general, approaches to
10 prolapse from surgical and nonsurgical
11 standpoint, the use of Prolift as a potential
12 alternative for surgical management of prolapse,
13 the methodology involved with doing the surgical
14 procedure, the complications that are seen
15 subsequent to the procedure, the information that
16 is provided in the IFU, the professional
17 education material for -- as well as the patient
18 brochure, and, finally, the specifics of the
19 treatment for Ms. Schubert.

20 Q. What you've just described is
21 essentially the scope of the opinions that you
22 have formed and that those are the areas you
23 intend to address, correct?

24 A. Those are the primary areas that I

1 intend to address. I mean, the areas that I
2 intend to address are indicated in my general
3 report on Prolift as well as on the information
4 that was the, I guess, disclosure, or whatever
5 you call it that -- of what I'm going to discuss
6 that was specifically written for this particular
7 case.

8 Q. You understand that the reason we take
9 your deposition is so that we can talk to you
10 directly and not rely on documents that may have
11 had input from lawyers or people other than
12 yourself? Do you understand that's why we talk
13 directly to you as to what issues you're going to
14 address and what your opinions are? You
15 understand that, right?

16 A. Yes, I understand that.

17 Q. The description you gave a moment ago
18 starting with addressing prolapse as a problem in
19 general and going down through the specifics of
20 Connie Schubert's treatment, as you sit here now,
21 those are the areas that you have formed opinions
22 on that you intend to address in this trial,
23 correct?

24 A. Yes. I mean, I also plan on

1 addressing in the trial my opinion regarding
2 Dr. Weber's opinions and approach to the
3 information in the Prolift that she has listed in
4 her 28 points of what should or should not have
5 been addressed.

6 Q. Let me ask you a question. Am I
7 correct that you do not know the full extent of
8 complications that were known to Ethicon Medical
9 Affairs at any particular point in time?

10 MS. JONES: Object to the form.

11 BY MR. SLATER:

12 Q. -- Prolift+M?

13 A. I know the -- I know complications --
14 I know information regarding complications that
15 were reported to Ethicon or that they were aware
16 of as part of the type of complications
17 associated with a specific mesh. I have not
18 specifically seen an email or a document that
19 says from Ethicon, these are all of the
20 complications we are aware of for this particular
21 product at this particular time in the use of the
22 product, a specific document saying that, I have
23 not.

24 Q. As you sit here now, did you see any

1 documents that indicated to you the full scope of
2 complications that were known to Ethicon with
3 regard to the Prolift at the time the Prolift was
4 first put on the market?

5 MS. JONES: Asked and answered, object
6 to the form.

7 THE WITNESS: It is my opinion that
8 there really -- that additional new and unusual
9 and unique complications that have occurred with
10 Prolift, I'm trying to think of any complication
11 that I am aware of that would not have been part
12 of what Ethicon would have been aware of based on
13 just mesh use in prolapse surgery in general.

14 BY MR. SLATER:

15 Q. But is there anything that you can
16 tell me to answer that question?

17 A. I think I just did.

18 MR. SLATER: Can I have the question
19 read back, please? And I'll ask you to just
20 directly answer the question.

21 (The record was read by the reporter.)

22 THE WITNESS: I don't recall seeing a
23 specific document, as I mentioned earlier, that
24 says exactly which complications Ethicon was

1 aware of at which point in time.

2 BY MR. SLATER:

3 Q. Do you know the scope of complications
4 related to the Prolift that was known to medical
5 affairs at Ethicon at the time the Prolift went
6 on the market?

7 A. Other than what would be typical for
8 any type of mesh in prolapse surgery, I don't
9 know whether there were anything specifically as
10 additional alternative -- or additional
11 complications that they were aware of.

12 Q. If I understand correctly, to the
13 extent that you believe certain complications or
14 risks were generally understood in the medical
15 community with regard to a device like the
16 Prolift, you believe that's what would have been
17 known to Ethicon Medical Affairs at the time the
18 Prolift went on the market. Do I understand you
19 correctly?

20 A. Yes.

21 Q. Do you have any knowledge as to
22 whether Ethicon had more extensive information
23 regarding the complications with regard to the
24 Prolift than what would have generally been known

1 or assumed in the general medical community at
2 the time the Prolift went on the market?

3 A. I don't have any knowledge that they
4 did or did not.

5 Q. If we could, let's mark -- what we
6 marked as Exhibit 4, what I was given that has a
7 title on it Dr. Nicolette Horbach Schubert
8 Reliant List.

9 (Exhibit No. 4 marked for identification.)

10 MR. OVERBY: They always leave me off.
11 It's okay. I'm used to it.

12 MR. SLATER: Extra in there, David? I
13 apologize.

14 MR. OVERBY: That's fine. I memorized
15 it from the email yesterday.

16 MS. JONES: You can have it.

17 BY MR. SLATER:

18 Q. Exhibit 4 has a title on it,
19 Dr. Nicolette Horbach -- Schubert Reliance List.
20 Can you tell me what this document is?

21 A. This is a compilation of all of the
22 documents that were forwarded to me regarding the
23 litigation for Ethicon, including both for the
24 Wicker case as well as for the Schubert case.

1 Q. Did you read and consider each of
2 these materials?

3 A. There are some of these materials that
4 I did not review specifically for the Schubert
5 case, no.

6 Q. Let me ask you this. Starting with
7 the section on transcripts, you list David
8 Robinson. Do you know which dates of deposition
9 transcripts you've reviewed for him?

10 A. I can probably make it easier for you
11 by saying that I can tell you which transcripts
12 I've specifically reviewed in this case, and that
13 includes the transcripts of the deposition for
14 Anne Weber that was taken in June 2013, the
15 deposition of Christopher Roberts, the deposition
16 of Connie Schubert as well as the deposition of
17 Lewis Wall. Those are the depositions that I've
18 read for this case in specific.

19 Q. So if I understand correctly, even
20 though you've read other deposition transcripts
21 listed there, you would not be relying on those
22 for your testimony in this case?

23 MS. JONES: I'm going to object to the
24 form of the question. I'm going to allow

1 Dr. Horbach to answer the question, but so that
2 I'm -- I need to put on the record, counsel, what
3 I discussed earlier in the sense that, though
4 this has the term --

5 MR. SLATER: Well, I don't want to do
6 this right now. I really at this point -- I
7 don't think it's an appropriate time for this.
8 I'm in the middle of a line of questioning, and
9 there is a question pending. So I don't think
10 it's appropriate, with all due respect, to put a
11 statement on the record while a question is
12 pending --

13 MS. JONES: Well --

14 MR. SLATER: -- that's a very direct
15 question.

16 MS. JONES: I will allow the witness,
17 but I'm going to object to the form of the
18 question based upon my discussion with you
19 earlier at the outset of the deposition where I
20 wanted to put on a statement on the record about
21 what this list is.

22 Dr. Horbach can answer it, but I'm going
23 to put a statement on here that clarifies what
24 this is that I've already discussed with you.

1 You may go ahead, Doctor.

2 BY MR. SLATER:

3 Q. Dr. Horbach, the materials you just --
4 rephrase.

5 Those depositions that you just identified
6 for me, is it your intention to rely on those
7 depositions that you specifically pointed to for
8 your testimony in this trial?

9 MS. JONES: Object to the form.

10 THE WITNESS: Yes, primarily, yes.

11 MS. JONES: Now, counsel, let me put
12 the statement on the record at this point --
13 you've gotten your answer -- that this list was
14 compiled by me yesterday essentially at your
15 request. It does include the materials that
16 Dr. Horbach has in her possession. She -- they
17 are intended to be a statement of materials in
18 her possession or that she has reviewed whether
19 or not she specifically relies upon those, and
20 there are some additional materials about which
21 you can ask her that are not on this list.

22 MR. SLATER: Okay. I'll get to those.

23 BY MR. SLATER:

24 Q. As you sit here now -- it says you

1 read David Robinson's transcripts. Do you know
2 what dates those were, those transcripts?

3 A. No. My comment was I didn't say that
4 I had done that. I have copies of David
5 Robinson's transcripts. I have glanced through
6 them, you know, in a little more briefer fashion
7 prior to my review of anything about Connie
8 Schubert. It was more relative to the
9 information on Wicker. So I can't give you the
10 specific dates. All that information's at home.

11 Q. Okay.

12 MS. JONES: Counsel, I'd be happy --

13 BY MR. SLATER:

14 Q. Is it fair to say -- let me continue.

15 Is it fair to say that, with regard to the
16 Ethicon employees listed here -- well, let me ask
17 you this. Do you know which of these people are
18 Ethicon employees that are listed on this list of
19 transcripts?

20 A. I know -- I recognize the names of
21 some of the individuals here as Ethicon
22 employees, yes.

23 Q. Which ones?

24 A. Williams, Robinson, I know that there

1 have been emails going back and forth with
2 Hinoul, I guess it is, so -- I think that's how
3 you pronounce that name -- as well as Gauld.

4 I don't recall whether I've seen emails or
5 information about Jessica Shen as an employee.
6 Obviously Dr. Lucente is not an employee. And
7 Ping Yu, I don't recall -- I'm trying to remember
8 whether I've seen specifics whether she was or he
9 was.

10 Q. Is it fair to say that, with regard to
11 the Ethicon employees whose transcripts you have,
12 you have not read them in their entirety?

13 A. That would be fair to say, yes.

14 Q. Would it be fair to say that, with
15 regard to each of those Ethicon employees who you
16 were provided transcripts from, you may have
17 glanced at them but you have not read them in
18 depth at all?

19 A. I have not read them in depth.

20 Q. As you sit here now, is it fair to say
21 you are not relying specifically on anything
22 stated in any of the depositions of the Ethicon
23 employees for your opinions?

24 A. Of those that I've -- of those

1 employees that I mentioned, yes, that's correct.

2 Q. Is it fair to say you're not relying
3 specifically on anything in Vincent Lucente's
4 deposition transcript for any of your opinions in
5 this case?

6 A. I have not read his in entirety at
7 this point in time, so, no -- yes, it would be
8 correct.

9 Q. Did you read Anne Weber's deposition
10 transcript from June 2013 in its entirety?

11 A. Yes.

12 Q. Did you read the deposition of
13 Christopher Roberts in its entirety?

14 A. Yes.

15 Q. Did you read the deposition of Connie
16 Schubert in its entirety?

17 A. Yes.

18 Q. Did you read the deposition of Lewis
19 Wall in its entirety?

20 A. Yes.

21 Q. Are you aware of who Dr. Wall is?

22 A. Yes.

23 Q. He's a nationally recognized medical
24 ethicist and a highly respected urogynecologist,

1 correct?

2 MS. JONES: Object to the form.

3 THE WITNESS: I think that Dr. Wall is
4 a nationally recognized ethicist and
5 humanitarian, and he does do a urogynecologic
6 practice, yes.

7 BY MR. SLATER:

8 Q. With regard to the specifics of Connie
9 Schubert's medical condition, would you defer to
10 Lewis Wall as her treating surgeon with regard to
11 those specifics?

12 A. No.

13 Q. Do you know when the last time was
14 that Dr. Wall saw Connie Schubert?

15 A. The last record I have was when she
16 was seen in July of 2013 at her four-week
17 postoperative visit.

18 Q. At that time Dr. Wall was seeing her
19 postoperatively to her July 10, 2013 surgery,
20 correct?

21 A. Yes.

22 Q. The surgery performed by Dr. Wall on
23 July 10, 2013 was extensive, correct?

24 A. I don't know that you can call it

1 necessarily extensive per se. I know he incised
2 tissue and dissected and closed the area. That
3 typically, to me, would not be referred to as
4 extensive.

5 Q. In July of 2013 Dr. Wall removed
6 eroded mesh from Connie Schubert's vagina and
7 pelvis, correct?

8 A. He did -- he removed some of the
9 synthetic mesh that was presumed to be the two
10 little blue areas that were seen on the
11 photograph.

12 Q. Is it your understanding that the two,
13 as you call them, the two little, blue areas on
14 the photograph, that that's the only mesh that
15 was removed from Connie Schubert during the July
16 10, 2013 surgery, just what's visible on those
17 photographs?

18 A. Not necessarily. He did -- he did
19 remove a piece of tissue that pathology read as
20 being a centimeter by .5 centimeters, that that
21 had tissue and mesh within it, so I can't tell
22 you how much of that was mesh and how much of
23 that was tissue.

24 Q. You understand that Dr. Wall did not

1 send everything he removed from Connie Schubert
2 down to pathology. You know that, right?

3 A. That's against hospital policy.

4 Q. You believe that every single bit of
5 tissue or mesh that Dr. Wall would have removed
6 would need to have been sent down to pathology?

7 A. That's JACO standards, yes.

8 Q. Once that material would have been
9 sent -- well, rephrase.

10 You would understand that the pathology
11 lab, when it received material from Dr. Wall,
12 would not keep all that material; it would sample
13 some of it and discard the rest. Do you know
14 that?

15 A. That's incorrect.

16 Q. Do you believe that in the state of
17 Missouri when a surgery is performed to remove
18 mesh and tissue that every bit of everything that
19 is removed needs to be preserved by the hospital
20 pathology lab? Is that your understanding?

21 A. I can't say that based on Missouri
22 law, but in this particular case, when you remove
23 a specimen, you do a gross assessment where you
24 do the measurement of the specimen, and there are

1 listed two specific areas that were removed and
2 the size and dimensions of that tissue, and then
3 you sample sections of it for microscopic
4 analysis. But you do measure the entire
5 aggregate or gross amount of the tissue that was
6 removed, yes. You don't just measure some of it
7 and not measure other parts of it, at least from
8 the gross description. You may not sample every
9 bit of it microscopically, but at least from the
10 gross description.

11 Q. When Dr. Wall operated on Connie
12 Schubert in July of 2013, he found eroded mesh
13 and he found contracted and scarred mesh as well,
14 correct?

15 A. Let me pull back his specific
16 operative report. I have the -- my summary
17 notes, but let me pull his specific operative
18 report.

19 All right. I have the operative report
20 now.

21 Q. You can see under the operative
22 findings that Dr. Wall commented in part, there
23 was a transverse mesh band at the vaginal apex
24 which was smaller than two fingers in diameter

1 with sharp edges clearly palpable and blue fibers
2 of mesh clearly visible. Do you see that?

3 A. Yes.

4 Q. That is contracted and scarred mesh
5 that had eroded through the vagina, correct?

6 A. I can't -- I mean, I can't know
7 whether or not the transverse band that he
8 specifically is referring to is mesh in its
9 entirety or it's part mesh and part contraction.
10 Oftentimes they may be --

11 THE REPORTER: Slow down for me,
12 please, Doctor. "Oftentimes they may be --"

13 THE WITNESS: Oftentimes during
14 surgery it is difficult to determine whether or
15 not the band that you're feeling is
16 specifically -- has mesh underneath it versus
17 simply scar.

18 BY MR. SLATER:

19 Q. Dr. Wall described it as a transverse
20 mesh band. Do you see that?

21 A. Yes, but he does not say the
22 measurements of the band.

23 Q. Doctor, my question is this -- move to
24 strike.

1 Dr. Wall refers to a transverse mesh band,
2 correct?

3 A. Yes.

4 Q. In the common vocabulary for this type
5 of surgery, that would mean that you had mesh
6 that had scar tissue that had formed around it
7 and contracted it down and made it hard and
8 tight, correct? That's what a transverse mesh
9 band would be in this context, right?

10 A. I don't -- I mean, I don't know what
11 he specifically is meaning when he says that.
12 All I have to do is be able -- that's a
13 subjective statement, and I have information to
14 look at objectively based on the path. report
15 that tries to give me information about the
16 extent of that band.

17 Q. Move to strike. I didn't ask you the
18 extent of the band, so --

19 A. Well --

20 Q. All I asked you was, if I'm correct
21 that what he describes there would be commonly
22 understood to be a combination of mesh and scar
23 tissue that would have contracted down and
24 hardened this mesh. That's the common

1 vocabulary, right?

2 MS. JONES: Object to the form.

3 THE WITNESS: Again, I don't know

4 whether that's what he's referring to, but he

5 says that there is a transverse mesh band at the

6 apex. So I would -- it could be just it's mesh,

7 it could be that it's mesh and tissue. I can't

8 tell you.

9 BY MR. SLATER:

10 Q. Your understanding would be that that

11 transverse mesh band referred to by Dr. Wall

12 would be either just mesh or mesh combined with

13 scar tissue, one or the other, correct?

14 A. Yes.

15 Q. Certainly Dr. Wall would have a better

16 understanding than you would have as to what he

17 actually saw and what he actually removed from

18 Ms. Schubert's body because he performed the

19 surgeries, correct?

20 A. Yes.

21 Q. You've referred to the pathology

22 report. The pathology report is quite terse with

23 regard to the specimens that were removed after

24 this surgery, correct?

1 A. Yes.

2 Q. One would not necessarily know exactly
3 what was removed from Connie Schubert or the
4 quality of what was removed from reading that
5 pathology report, correct?

6 A. No.

7 Q. Not correct?

8 A. No. I said to you specifically before
9 that the pathologist is required to measure and
10 at least -- the gross specimen, and that's what
11 they have indicated on the pathology report. So
12 there is a measurement of the two gross --
13 G-R-O-S-S -- specimens as well as sampling of one
14 of the specimens.

15 Q. When one looks at the pathology
16 report, do you have an understanding of the
17 quantity of material that was measured by the
18 pathologist -- that's one of the things there,
19 correct?

20 A. Yes.

21 Q. Beyond that, the pathologist did not
22 provide much information about the specific
23 quality or characteristics of what was removed,
24 correct?

1 A. No. Well, I'm not saying -- no, I
2 can't answer -- I can't -- I would not agree with
3 that. The pathologist says that they removed or
4 that they investigated one portion of the
5 specimen that was removed, which I presume is the
6 part that did not necessarily have the mesh in
7 it, and said that there was simply -- trying to
8 find this reference here -- I think it was
9 epithelial tissue or something. It does not
10 describe that there was actually foreign body.
11 It appears as if the pathologist only sampled
12 perhaps one of the area.

13 Q. The pathologist actually -- well,
14 rephrase.

15 The vaginal tissue would be epithelial
16 tissue, correct?

17 A. Yes.

18 Q. The pathologist actually calls the
19 tissue squamous mucosa, which would be an
20 inaccurate description of vaginal tissue,
21 correct?

22 A. No.

23 Q. Do you believe that epithelial tissue
24 is the same thing as mucosa?

1 A. No. The vagina is made up of squamous
2 epithelium.

3 Q. The vagina -- the vaginal tissue is
4 epithelial tissue; it's not mucosal tissue,
5 correct?

6 A. We've referred to the vaginal wall as
7 a squamous epithelium, and we will use the terms
8 interchangeably, epithelium and mucosa, to
9 describe the lining of the vagina.

10 Q. Okay. Ultimately, the pathologist, as
11 you described it, did an analysis of a portion of
12 tissue and made a very terse report on it, and
13 that's all the information we have from the
14 pathology, correct?

15 A. Well, he said that the soft tissues
16 were submitted in total, so -- and he made the
17 comments about what he saw. So there was no
18 histologic abnormality on the soft tissues that
19 he saw.

20 Q. Do you know what the pathologist meant
21 when he said no histo -- rephrase.

22 Do you know what the pathologist meant
23 when he said that there was no histopathologic
24 abnormality with the tissue that he sampled?

1 A. Typically that would be interpreted as
2 there were not any other abnormal cell findings
3 such as chronic inflammation, such as, you know,
4 granuloma, such as inflammatory cells.

5 Typically, as in her first pathology
6 report, they did mention that there was a chronic
7 inflammation seen at the time of the pathology
8 report. That was not -- that was specifically
9 stated as not being present at the time of the
10 second pathology report.

11 Q. Well, there is no description one way
12 or the other with regard to -- rephrase.

13 The pathologist does not talk one way or
14 the other about the term chronic inflammation,
15 granulomas, inflammatory cells. He doesn't use
16 those terms, correct?

17 A. No, you're wrong. He specifically
18 says they weren't there. He says specifically
19 there's no histo -- histopathologic
20 abnormalities, so he is telling you that those
21 changes were not seen.

22 Q. Well, the pathologist doesn't use the
23 term chronic inflammation or no chronic
24 inflammation. He doesn't say that, right? Do

1 those words appear in the report?

2 A. On his report? On that particular
3 report? No, but on the --

4 Q. --

5 A. -- on the previous report --

6 Q. He doesn't use the word -- Doctor,
7 it's a very simple question.

8 MS. JONES: Let --

9 BY MR. SLATER:

10 Q. Okay? Does the pathologist use the
11 word "chronic inflammation" one way or the other
12 in this report?

13 A. No.

14 Q. Does he use the word "granulomas" in
15 this report?

16 A. No.

17 Q. Does he use the word "inflammatory
18 cells" in this report?

19 A. No.

20 Q. He states with regard to the portion
21 of tissue that he actually analyzed that that
22 portion of the tissue had no histopathologic
23 abnormality, correct?

24 A. Yes.

1 Q. One of the things Dr. Wall did in July
2 of 2003 was he made an effort to treat the
3 vaginal anatomic distortion that Mrs. Schubert
4 was suffering from, correct?

5 A. Surgery from 2013, I think you mean,
6 rather than 2003. Yes, he says that he did a
7 vaginoplasty as part of his procedures and
8 describes cutting through tissue and then
9 suturing it closed.

10 Q. I'm just going to ask the question
11 again because, you're right, I missed by a
12 decade.

13 One of the things Dr. Wall did in July of
14 2013 is he treated as best he could the vaginal
15 anatomic distortion that Mrs. Schubert was
16 suffering from, correct?

17 MS. JONES: Object to the form.

18 BY MR. SLATER:

19 Q. Is that a true statement?

20 A. Distortion I would -- I mean, I
21 don't -- I can't necessarily -- I won't answer
22 that based on distortion. He corrected the
23 anatomy that he found at the apex of the vagina.

24 Q. The anatomy at the apex of Connie

1 Schubert's vagina was significantly irregular,
2 correct?

3 A. He doesn't describe it as irregular.
4 He describes it as being narrowed.

5 Q. Well --

6 A. That's different.

7 Q. Compared to a normal vaginal apex, it
8 was not normal, right?

9 A. That -- that is true, yes.

10 Q. The surgery that Dr. Wall performed in
11 July of 2013 was necessitated at least in part by
12 the fact that Connie Schubert had a Prolift and a
13 Prolift+M placed in her body previously, correct?

14 A. Yes.

15 Q. So the Prolift and Prolift+M surgeries
16 contributed at least in part to the need for this
17 surgery and this treatment for these
18 complications, correct?

19 MS. JONES: Form.

20 THE WITNESS: Yes. Yes.

21 BY MR. SLATER:

22 Q. And in fact all of the treatment
23 Connie Schubert had of a surgical nature from --
24 after her initial surgery in December 2008 was

1 necessitated at least in part by the Prolift
2 surgery and then the Prolift+M surgery, correct?

3 MS. JONES: Object to the form.

4 THE WITNESS: Necessitated -- let me
5 just clarify it. The -- she had surgery done to
6 treat issues of the mesh. Whether that surgery
7 was indicated at each time that she was treated,
8 that I may not totally agree with. I think that
9 there are sometimes alternative measures that can
10 be done. But if she was going to end up having
11 surgery for removal of eroded mesh, then, yes,
12 that was -- that mesh was from the Prolift.

13 BY MR. SLATER:

14 Q. Okay. I understand. Let me ask the
15 question cleaner. After the Prolift was
16 initially put in Connie Schubert's body, she had
17 multiple procedures either in the office or in
18 the operating room to revise or remove mesh and
19 then ultimately to try to fix the shape of her
20 vaginal apex. That happened over the course of
21 time, correct?

22 A. Yes.

23 Q. The cause of those surgeries at least
24 in part was the fact that the Prolift had been

1 put in her body and then the Prolift+M was put in
2 her body, correct?

3 MS. JONES: Object to the form.

4 THE WITNESS: Yes.

5 BY MR. SLATER:

6 Q. In other words, these complications
7 that Connie Schubert had would be properly termed
8 Prolift and Prolift+M complications that
9 needed -- that were ultimately treated, correct?

10 MS. JONES: Form.

11 THE WITNESS: Yeah. Yes.

12 THE REPORTER: I'm sorry?

13 THE WITNESS: I said not just
14 potentially from the Prolift, but yes.

15 BY MR. SLATER:

16 Q. Certainly the Prolift and Prolift+M
17 were significant contributing factors to these
18 complications, correct?

19 MS. JONES: Object to the form.

20 THE WITNESS: They were contributing
21 factors.

22 BY MR. SLATER:

23 Q. You're not going to offer an opinion
24 that if Connie Schubert had had a different

1 surgery in December of 2008 what the outcome of
2 that surgery would have been, correct?

3 A. No, I don't think I would be --

4 Q. It would be speculation, right?

5 A. Yes. I don't think I would be able to
6 offer that unless I was clairvoyant.

7 Q. Well, if you are, I would like to
8 invite you to the racetrack or the casino after
9 this deposition.

10 A. Wish that was the case, but, no.

11 Q. You with agree with me that at the
12 time Connie Schubert was initially treated in
13 December of 2008 she had multiple reasonable
14 options, not just the Prolift, correct?

15 A. She had multiple other options, yes,
16 for treatment.

17 Q. One of the reasonable options for
18 Connie Schubert at that time would have been to
19 do no surgery, watch her condition, do exercises
20 and just see how she progressed. That would have
21 been a reasonable option, correct?

22 MS. JONES: Object to form.

23 THE WITNESS: I can say that it would
24 have been a reasonable option to do no surgery

1 and see how she progresses. I don't think that
2 exercises are going to make any difference in
3 this case.

4 BY MR. SLATER:

5 Q. One option -- rephrase.

6 One reasonable option for Connie Schubert
7 as of December 2008 would have been to have no
8 surgery and just watch and wait and see how she
9 did and see if she could live with her symptoms,
10 correct?

11 A. That is one option, yes.

12 Q. One option that would have been a
13 reasonable option for Connie Schubert would have
14 been to just have an anterior colporrhaphy and no
15 other surgical treatment, correct?

16 MS. JONES: Object to the form.

17 THE WITNESS: I disagree with that.

18 BY MR. SLATER:

19 Q. Why?

20 A. Based on the surgeon's description
21 that there was an enterocele present at the time
22 of her original examination prior to the Prolift
23 placement and anterior repair lobe will not
24 correct an enterocele.

1 Q. Do you have an understanding to a
2 reasonable degree of medical probability as to
3 the extent of an enterocele that Connie Schubert
4 had before the first surgery in December 2008?

5 A. No, but it doesn't make any
6 difference.

7 Q. The answer to my question is no,
8 correct?

9 A. Correct. The answer is no.

10 Q. There are enteroceles -- well,
11 rephrase.

12 An enterocele can present with varying
13 severities, correct?

14 A. Yes.

15 Q. -- and some would not, correct?

16 A. I'm sorry. Half that question went
17 away.

18 Q. Sure. Depending on the severity of an
19 enterocele, some may require surgery from your
20 perspective and some may not, correct?

21 A. If you're only treating an enterocele
22 as the only problem, yes, I agree with that
23 statement, but you can't treat an anterior
24 prolapse in the place of an enterocele and leave

1 an enterocele untreated without increasing the
2 risk that the patient is going to have a more
3 rapid deterioration of their apical support
4 and/or recurrence of -- or progression of their
5 enterocele requiring further surgery, or,
6 alternatively, if you only do an anterior repair
7 and you try to treat the enterocele at the same
8 time with just an anterior repair, you'll result
9 in vaginal shortening.

10 Q. So if I understand correctly, you
11 think that if the decision had been made to do an
12 anterior colporrhaphy that a procedure would have
13 also been needed just to support the apex due to
14 the fact that there was an enterocele of some
15 degree as well.

16 A. Yes.

17 Q. Do I understand you correctly?

18 A. Yes, that would need to be treated.

19 Q. I'm sorry. And what would have been
20 the reasonable options to treat the enterocele in
21 conjunction with the anterior colporrhaphy?

22 A. There is the option of a transvaginal
23 enterocele repair. There is the option -- and
24 that can be done in multiple different ways of

1 a -- some form of a McCall's type of suspension.
2 There is the possibility of doing a sacrospinous
3 ligament fixation with repair of the enterocele
4 to support the apex. There is the possibility of
5 doing a uterosacral ligament suspension, but that
6 is usually much more challenging to do in a
7 post-hysterectomy patient as the ligaments can be
8 more difficult to find. Or there was the option
9 of proceeding with an abdominal approach for
10 apical support and correction of the enterocele.

11 Q. And all of those options from your
12 perspective would have been reasonable options
13 for Connie Schubert, correct?

14 A. I think that there -- I mean,
15 reasonable is hard to say because it would depend
16 a little bit more on her anatomy before I would
17 make a decision about what would be a more or
18 less reasonable option.

19 Q. Okay. So you're not going to form an
20 opinion on that issue as we sit here now,
21 correct?

22 A. I'm not going to form an opinion on
23 what should have been done as an alternative?

24 Q. Well, what of that list of options

1 would have been reasonable options for her? You
2 said you would need more information to give that
3 opinion. Do I understand you correctly?

4 A. I think all of them would be
5 reasonable options from a hypothetical,
6 theoretical standpoint. In this individual
7 patient they all might be reasonable options as
8 well, but when I make a recommendation for a
9 patient, at least myself, I take into account
10 other aspects of anatomy. But those are all --

11 Q. With regard to --

12 A. Do you want me to finish?

13 Q. Yes, I do. I apologize.

14 A. But those are all reasonable options
15 that can be used for treatment of a patient who
16 has a similar description on exam.

17 Q. With regard to Connie Schubert
18 specifically as a patient, you're not able to
19 form an opinion to a reasonable degree of medical
20 probability as to which of these options would
21 have been reasonable for her because you would
22 need more information to give that opinion. Do I
23 understand you correctly?

24 A. Yeah, I guess so, I mean... yeah, I

1 guess so. I'd have to be -- I'd have to examine
2 before I would myself make a decision. I think,
3 you know, from a global medical perspective, I
4 think that different surgeons may choose any of
5 those as options. That's the hard part about our
6 surgical specialty is that it's an art as much as
7 it is a science -- or actually probably an art
8 more than it is a science.

9 Q. There was a note pre-operatively in
10 Dr. Roberts' records referring to dyspareunia.
11 You saw that, right?

12 A. Yes.

13 Q. Do you know specifically what he was
14 referring to when he used the term dyspareunia?
15 I don't mean what the general understood
16 definition is, but I want to know if you know
17 what specific symptoms he was referring to with
18 regard to Connie Schubert.

19 A. He didn't specify anything more than
20 that, so I can't -- I don't know what he means by
21 that specifically.

22 Q. -- in general terms, doctors use the
23 word dyspareunia to cover a whole range of
24 different levels of symptoms or complaints that

1 they might include under that definition, so
2 you'd need to know more to know exactly what her
3 specific symptoms were, fair?

4 A. I think dyspareunia can cover a
5 variety of different types of complaints, yes.

6 Q. Do you know whether Connie Schubert
7 was sexually active and had a satisfying sexual
8 life right up until the time of the December 2008
9 surgery one way or the other?

10 A. She reports in her deposition that she
11 was sexually active and had viewed that as being
12 satisfying prior to the surgery.

13 Q. Did you review a clinical expert
14 report in this case with regard to the Prolift or
15 Prolift+M?

16 A. I reviewed a clinical expert report
17 that was done by David Robinson, I believe. That
18 was dated, I believe, in 2011.

19 Q. Okay. Did you form any opinions one
20 way or the other based on that clinical expert
21 report?

22 A. I think his report was part of the
23 information that I reviewed in forming my
24 opinions, but I can't specifically tell you which

1 specific opinion was only based on that
2 information.

3 Q. Do you know, as you sit here now, what
4 medical affairs in Ethicon knew or thought with
5 regard to the causes or the consequences of mesh
6 contraction with the Prolift or Prolift+M?

7 A. Do I know what they knew about the
8 causes? No, I don't think I can say specifically
9 whether they knew what, you know, what -- I
10 don't -- I can't specifically say whether they
11 knew or not what the consequences of using
12 Prolift or Prolift+M or a mesh in the vagina
13 could end up causing. I don't know what their
14 extent was of knowledge.

15 Q. Let me ask you a question. Let's come
16 back to Exhibit 4, if we could. This is your
17 so-called reliance list. I started to ask you
18 this before, and I want to go through it a little
19 bit. We went through the transcripts. I'd like
20 to look now at the section that says Expert
21 Reports. Do you see that?

22 A. Yes.

23 Q. -- reports from cover to cover?

24 A. I'm sorry. Did I what?

1 Q. Did you read each of the listed expert
2 reports from cover to cover?

3 A. I have read, I think, them from cover
4 to cover, not as recently, though, because some
5 of these I read in evaluation of the Wicker case.

6 Q. I just want to be clear because I
7 might have just spaced out for a second. Did you
8 say that you read each of these expert reports
9 from cover to cover at some point?

10 A. Yes, I believe so.

11 Q. Okay. Was the information found in
12 these expert reports of importance to you in
13 forming your opinions?

14 A. Some of them were; some of them
15 weren't.

16 Q. Was the information in Dr. Elliott's
17 report of importance to you in forming your
18 opinions?

19 A. I can't -- I can't give you the
20 specifics about that because they were -- I read
21 them a while back, and so what -- which piece of
22 information from which expert report I relied in
23 creating a global opinion I won't be able to
24 answer that even if you go down the entire list.

1 Q. Am I correct that with regard to each
2 of these expert reports you at least had that
3 information available to you and it's something
4 that you would have known about at some point?

5 A. Yes.

6 Q. With regard to Dr. Klinge's expert
7 report, is that something you took into account
8 in forming your opinions?

9 A. It was part of the information that
10 I've used in forming my opinion, yes, his report
11 plus the work he's done in the literature.

12 Q. You're familiar with who Dr. Klinge
13 is?

14 A. Yes.

15 Q. You're aware that he's a
16 world-renowned expert with regard to the
17 materials that are used in the various meshes for
18 surgical treatment in the pelvis and abdomen?

19 MS. JONES: Object to the form.

20 THE WITNESS: I'm aware that he is --
21 that his research is in areas of the tissue
22 response of meshes in the abdomen primarily,
23 although he has done some work in the pelvis.

24 BY MR. SLATER:

1 Q. Did you -- well, rephrase.

2 Do you know to what extent -- withdrawn.

3 Withdrawn.

4 Would you agree with me that the
5 contraction of the Prolift mesh was a
6 contributing factor to the recurrence of prolapse
7 that ultimately occurred with Connie Schubert?

8 MS. JONES: Object to form.

9 THE WITNESS: I think it could be a
10 contributing factor. I can't tell you for sure
11 that it was absolutely a contributing factor.

12 BY MR. SLATER:

13 Q. It may not have been. You can't say
14 better than that? Fair?

15 A. I think that it potentially had a part
16 of the -- it had a role in contributing
17 potentially to her -- her recurrent prolapse. We
18 don't totally understand in every single patient
19 what all of the factors are that create a
20 recurrence of prolapse. So we make a hypothesis
21 of factors that we think are related to it.

22 Q. It's certainly understood with the
23 type of contraction of mesh that was documented
24 in the operative reports for Connie Schubert that

1 contraction of that nature in that location can
2 lead to a recurrence of prolapse as Connie
3 Schubert actually experienced, correct?

4 A. I think --

5 MS. JONES: Object to the form.

6 THE WITNESS: I think that the -- I
7 can't answer -- I don't agree with that statement
8 in part because the area of contraction that is
9 oftentimes referred to is usually more in the
10 area distally where the graft may pull superiorly
11 making the patient more at risk for a distal type
12 of recurrence, or, alternatively, could the graft
13 pull medially and make the patient more at risk
14 for more lateral issues.

15 In this particular case the patient
16 developed a recurrence that was superior to the
17 proximal edge of the anterior mesh, and,
18 therefore, it would be a little more difficult to
19 postulate from a mechanistic standpoint that the
20 contraction of the mesh alone was responsible for
21 creating that.

22 Q. You would agree with me that it's
23 likely that the contraction of the Prolift mesh
24 was a contributing factor to the occurrence of

1 the -- recurrence of the prolapse, correct?

2 MS. JONES: Object to the form.

3 THE WITNESS: I can't answer that per
4 se. I think it's possible, but I can't say that,
5 yes, you know, for medical certainty that it was
6 absolutely a contributing factor.

7 BY MR. SLATER:

8 Q. You can't say one way or the other,
9 it's possible one way or the other? Do I
10 understand correctly?

11 A. Well, first of all, the whole issue of
12 contracture of the mesh, it is unclear whether
13 that contracture, quote/unquote, or fold or
14 whatever you want to call it that Roberts refers
15 to is proximal or distal to the location of where
16 the recurrence was. That information isn't
17 clearly spelled out. So the difficulty is that,
18 if the mesh -- if the recurrence was distal to
19 that area, then the mesh probably didn't have a
20 role to play in it because the mesh was still
21 covering that aspect.

22 Q. As you sit here now, are you familiar
23 with any internal documents within Ethicon's
24 records where people in medical affairs or others

1 analyzed the subject of contraction and
2 recurrence in such a way that it would cut for or
3 against connecting the contraction of Connie
4 Schubert's mesh to her recurrence?

5 A. I'm sorry. Is there a way to
6 rephrase? You're gone again.

7 Q. -- any --

8 A. Sorry. You were gone again.

9 Q. Are you familiar with any internal
10 Ethicon documents analyzing the connection
11 between contraction of mesh and recurrence of
12 prolapse?

13 A. I'm familiar with emails discussing
14 that aspect of whether or not that may be a
15 factor in contributing to recurrent prolapse.

16 Q. Are you aware of whether medical
17 affairs at Ethicon believed that contraction of
18 mesh was a contributing factor to recurrence?

19 A. I don't know whether they were
20 specifically aware, no.

21 Q. The contraction of the Prolift mesh is
22 a complication, correct?

23 A. Yes.

24 Q. The erosion of the Prolift mesh is a

1 complication, correct?

2 A. Yes.

3 Q. The contraction and erosion of the
4 Prolift+M mesh, that is -- well, rephrase. I'll
5 ask it broken down.

6 The contraction of Prolift+M mesh, that is
7 a complication, correct?

8 A. Yes.

9 Q. The erosion of the Prolift+M mesh was
10 a complication, correct?

11 MS. JONES: Object to the form.

12 THE WITNESS: If indeed the mesh that
13 eroded was the Prolift+M mesh at a subsequent
14 time, yes, that would be -- that would be a
15 complication of the procedure. I think that
16 there is perhaps some debate about what actually
17 eroded subsequent to the time of the Prolift+M
18 being placed, how much of it was Prolift itself
19 versus Prolift+M.

20 BY MR. SLATER:

21 Q. It's difficult for you to tell because
22 the Prolift had been put in, portions had been
23 revised and removed, and then an anterior
24 Prolift+M was put in with Prolift mesh remaining

1 in her body, correct?

2 A. Correct, so that the mesh that came
3 out was either Prolift+M or Prolift itself, yes,
4 either one.

5 Q. To the extent that Dr. -- rephrase.

6 If, hypothetically, Dr. Roberts had
7 removed the entire anterior part of the Prolift
8 other than the arms, if that had happened, the
9 contracted mesh and the eroding mesh in the
10 anterior part of the vagina would have been
11 Prolift+M mesh after the Prolift+M was put in,
12 correct?

13 A. Yes.

14 Q. Did you have an opinion to a
15 reasonable degree of medical probability as to
16 whether that scenario is likely what occurred
17 here?

18 A. I think it probably did, yes.

19 MS. JONES: Counsel, when you get to a
20 stopping point --

21 MR. SLATER: Do you guys want to eat
22 soon?

23 MS. JONES: Well, I'm going to have to
24 send somebody down. I mean, even if we take a

1 quick break and come back for a minute while
2 we --

3 MR. SLATER: You know what? This is a
4 good time. Let's break. Fine. We're making
5 good progress.

6 VIDEO SPECIALIST: The time now is
7 12:45. We are going off the record. This is the
8 end of disk number 1.

9 (Proceedings recessed.)

10 VIDEO SPECIALIST: The time now is
11 1:44. We are back on the record. This is the
12 beginning of disk number 2.

13 BY MR. SLATER:

14 Q. Okay. Dr. Horbach, I'm going to ask
15 you some more questions about Exhibit 4, the list
16 of reliance materials.

17 A. Okay.

18 Q. On the second page there is a heading
19 that says Employment Records.

20 A. Mm-hmm.

21 Q. Is there anything in those employment
22 records that was of significance to you in
23 forming your opinions in this case?

24 A. Yes.

1 Q. What?

2 A. The information -- there are several
3 pieces of information for her employment records.
4 Specifically the association with her working at
5 her employer, the Justin Brands, around the time
6 that the patient experienced her symptoms of
7 prolapse, and the level of activity that she was
8 doing at that time in her job, the amount of
9 physical exertion that she was doing in her job.

10 In addition, during that time period she
11 also had filed or she also was filing components
12 of workman comp for activities that were
13 associated with her job, and that that in and of
14 itself, the lifting of this cement bucket of
15 something or other was associated with triggering
16 part of her bladder problems as well as her
17 all-over body problems that she mentioned, and
18 certainly with the physical exertion she's doing,
19 that can make her at increased risk for
20 developing issues of the prolapse.

21 In addition, the employment records that
22 go from her postoperative time period after her
23 original surgery and the aspect of going back to
24 work, and, you know, full-time, and when she was

1 doing that as well as potentially then increasing
2 the rate -- the risk of her having a problem with
3 a recurrence of a prolapse. She also eventually
4 -- hang on. Let me get back to my section where
5 I wrote my notes, if I can find it. Okay. I'm
6 sorry.

7 So that she is, during that time of her
8 employment with Justin Boots, she is stating, as
9 part of her workman's comp complaint, that her
10 injury, that is, i.e., the prolapse began
11 December 1st at work and was, therefore, a
12 work-related problem. She, you know,
13 subsequently had her surgery. She returns to
14 work, and then at one point ends up having -- at
15 one point is no longer working at the boot or
16 Justin Brands, whatever that is.

17 And then subsequently some of the
18 discussion regarding her employment when she was
19 working at Casey's and her level of activity, her
20 full-time work essentially that occurred until
21 she was terminated in August of 2012 gives me
22 information a little bit about her level of
23 physical activity.

24 Her information in her disability claim

1 that was filed in January 2013 relative to her
2 physical activity seems to be in contradiction to
3 some of the other information that she has
4 provided relative to how physically active she
5 was at her job, how much lifting, et cetera she
6 was doing.

7 So I looked at that relative to risk
8 factors for her prolapse initially, risk factors
9 for her recurrence of prolapse, and risk factors
10 associated with or issues associated with her
11 level of physical activity/disability.

12 Q. What are you reading from?

13 A. I am reading from -- I keep a summary
14 of notes that I take when I read through a
15 medical record just, I guess, like you-all
16 probably do. So it just has dates and times or
17 dates and what was going on at that time so I
18 don't have to go through the entire medical
19 record to find the information.

20 Q. All right. What I'd like to do is
21 mark all your notes right now as an exhibit.

22 A. I figured so. That's fine.

23 MS. JONES: I don't have any objection
24 to marking all of the notes, but what I would

1 like to do is to let her continue to look at
2 them -- she has got them organized by what she
3 was reviewing at a given time.

4 We can't hear a word you're saying.

5 THE WITNESS: Sorry. Can't hear you.

6 MR. SLATER: I have no problem,
7 Christy, with her continuing to use the notes,
8 but I want to mark them and we're going to have
9 to get copies, you know, made so that the court
10 reporter can take copies.

11 MS. JONES: That's fine. That's fine.

12 THE WITNESS: Mark them right now?

13 MR. SLATER: Mark it now, all your
14 notes. Let's mark them -- I think we premarked a
15 few exhibits. I'm not sure I'm going to get to
16 all of them, but let's start at Horbach 10.

17 MS. JONES: Do you want each thing
18 marked separate or do you want them all together?

19 MR. SLATER: One is 10, one is 11, one
20 is 12, and so on, so forth.

21 (Exhibit Nos. 10, 11 and 12 marked for
22 identification.)

23 THE WITNESS: I guess that tablet is
24 the next one.

1 MR. SLATER: That's all the notes?

2 There are no other notes.

3 THE WITNESS: Not regarding medical
4 issues and -- medical histories and summaries and
5 other things like that.

6 MR. SLATER: I want notes on anything,
7 any of your notes that you've taken.

8 MS. JONES: Adam, the only -- let me
9 say that the other --

10 MR. SLATER: I mean, if they are
11 setting on the table, if there are notes that are
12 set setting on the table that she is using to
13 help her know what things happened or whatever --

14 THE WITNESS: No, the rest of it is
15 not. They are just tagged things that have where
16 -- when things occurred where -- or actually I
17 don't think I used --

18 MR. SLATER: I don't care about
19 Post-It notes.

20 MS. JONES: That's what the other
21 stuff is, is Post-It notes that are on the
22 records themselves.

23 THE WITNESS: I mean, I don't know if
24 you want to -- this is a summary of, like, the

1 statements out of Wall's deposition, Dr. Wall's
2 deposition. So I don't know if you want --

3 MR. SLATER: Sure. Might as well
4 because then I don't have to ask you about it and
5 we can get done a lot quicker.

6 THE WITNESS: They are direct quotes
7 from parts of the deposition.

8 MR. SLATER: That's fine. If we mark
9 it, then I'm not one of these -- I'm not going to
10 have them sent to me and question about it.

11 (Exhibit Nos. 13 and 14 marked for
12 identification.)

13 MS. JONES: All right. They are
14 marked, Adam.

15 BY MR. SLATER:

16 Q. So let's go back on and we'll identify
17 them for the record and we'll continue.

18 MS. JONES: Do you want me to just
19 have the doctor identify them as exhibits?

20 MR. SLATER: Are we still on the
21 record?

22 MS. JONES: Yeah, we've been on the
23 record.

24 MR. SLATER: Oh, okay.

1 BY MR. SLATER:

2 Q. Dr. Horbach, we've just marked your
3 notes. Starting with Horbach 10, what is that
4 exhibit? What is that document?

5 A. It is a clinical summary of the
6 patient's medical record from sources other than
7 specifically Dr. Roberts' or Dr. Wall's care.
8 It's other medical issues that she has had,
9 visits with her primary care physician, visits
10 with her -- with, you know, orthopaedic people.
11 Just summarizes her chronologic history.

12 Q. What is Horbach 11?

13 A. Horbach 11 is a summary of her answers
14 to interrogatories. I mean, it's only a single
15 page.

16 Q. What is Horbach 12?

17 A. Horbach 12 is a clinical chronology of
18 her medical care associated with Dr. Roberts and
19 following with Dr. Wall, both on the office as
20 well as notes from the hospitalizations.

21 Q. Is there another exhibit?

22 A. Yeah, one more.

23 Q. 13?

24 A. 13. Actually two more. Number 13 are

1 notes regarding, you know, issues that I
2 potentially would be covering in my expert
3 opinions. When you had asked me previously what
4 were my opinions going to be, these were simply
5 just supplemental notes for me regarding -- from
6 my report and also regarding Connie Schubert of
7 opinions.

8 And the last is Exhibit 4 -- sorry, 14 --
9 which is a combination of summary from Dr. Wall's
10 deposition, chronologically what he said in
11 pages, et cetera, and also some from Dr. Weber's
12 definition -- or deposition -- regarding some of
13 her concerns with Prolift.

14 BY MR. SLATER:

15 Q. So Exhibits 10, 11, 12, 13 and 14 are
16 all the notes that you prepared in order to get
17 ready for this deposition and to give your
18 opinions?

19 A. Other than if I've read an article,
20 sometimes I will write down, you know, what the
21 specifics of an article is per se, but these are
22 only -- these are really the clinical notes, yes.

23 Q. Well, I just need to know what else
24 there is that you're -- that you've written down

1 that reflects what your thoughts or opinions are,
2 and you're telling me there's the pads that we've
3 just marked. Then you might have put Post-It
4 notes or written onto actual articles or
5 documents, correct?

6 A. Yes. Yes, those are not where --

7 Q. And that's it?

8 A. Yes, that's correct.

9 Q. Now, let's talk a little bit about the
10 employment records that you talked about a few
11 moments ago.

12 A. Okay.

13 Q. First of all, you're not basing your
14 medical opinions on a claim that was made in a
15 workers' compensation petition or similar
16 document; you base your medical opinions on
17 medical documents and medical records and
18 testimony of doctors and Connie Schubert,
19 correct?

20 A. Well, her -- that's correct in part,
21 but her documents that she filled out as part of
22 workman's comp. and as part of her disability
23 claim are medical documents regarding the
24 patient. That's not -- they are not in isolation

1 to the patient's care and they are not in
2 isolation relative to the particular issues that
3 this patient is having. So it has --

4 Q. You said something about --

5 A. Sorry. Go ahead.

6 Q. You said something about her lifting
7 cement. Do you know how heavy the so-called
8 cement was?

9 A. She has reported in parts of her
10 records that she never lifted more than 11
11 pounds, but then in her disability claim she says
12 that during that job she lifted between -- up to
13 25 plus pounds on a regular basis.

14 Q. Well, do you have any idea what the
15 actual weight is of the so-called cement was that
16 she lifted?

17 A. No, I don't think there is any way
18 that I would have that information.

19 Q. Do you have an opinion to a reasonable
20 degree of medical probability as to why Connie
21 Schubert had pelvic organ prolapse that was
22 initially treated by Dr. Roberts on December 8,
23 2008?

24 A. I have an opinion regarding risk

1 factors that she had that are typically known to
2 contribute an increased risk to women developing
3 pelvic organ prolapse.

4 Q. I understand that. You're saying that
5 there are some factors in her background that
6 could contribute. Do you have an opinion to a
7 reasonable degree of medical probability when
8 you're saying this is the reason why she got
9 prolapse?

10 A. I think I can give you within a
11 reasonable degree of medical certainty the
12 combination of factors. There's never one single
13 factor typically that causes prolapse in an
14 individual.

15 Q. What is your opinion?

16 A. Regarding the factors that are
17 associated with it?

18 Q. I don't want a general description of
19 factors associated with prolapse. That's not my
20 question.

21 A. I understand that. You want --

22 Q. My question is this -- here's my
23 question. Do you have an opinion to a reasonable
24 degree of medical probability as to why Connie

1 Schubert ended up having pelvic organ prolapse
2 that was treated on December 8, 2008?

3 A. That's what I'm trying to answer for
4 you, that the contributing factors that are
5 within my opinion contributing to her developing
6 prolapse in her specific case.

7 Q. What are they?

8 A. First of all --

9 Q. Why did she get prolapse?

10 A. First of all, she is Caucasian, which
11 significantly is going to increase her risk
12 relative to if she were non-Caucasian.

13 Secondly, she had a hysterectomy performed
14 and at a young age and post-hysterectomy she was
15 at increased risk. She also had her ovaries
16 removed at a very young age with intermittent use
17 of hormone replacement. And so the lack of
18 estrogen in the tissues will typically
19 deteriorate the tissues, and we will see an acute
20 exacerbation oftentimes following a patient going
21 through menopause and the degree of prolapse that
22 they experience.

23 Third issue or another issue was from a
24 physical standpoint how much a patient does

1 lifting or not lifting can be -- contribute to
2 the problems of pelvic organ prolapse. And I
3 cannot tell you in this particular patient
4 what -- whether 5% was due to this or 10% is due
5 to that, et cetera. I mean, that's an
6 impossibility for anyone to say for an individual
7 patient, but it is the global components that are
8 associated with her particular situation that I
9 think are at risk for her developing prolapse.

10 Q. You said that lifting can contribute
11 to prolapse.

12 A. Yes.

13 Q. In this case you can't say whether or
14 not Connie Schubert lifting anything actually was
15 a cause of her prolapse, correct?

16 A. No. I think that's incorrect. I
17 think I'm more -- I think I'm more -- I'm able to
18 say with more probability than not that her
19 physical occupation had increased her risk of
20 developing pelvic organ prolapse.

21 Q. Increased the risk. Here's my
22 question: Is it your opinion, yes or no, or you
23 don't have an opinion, that the physical activity
24 of Connie Schubert's occupation contributed to or

1 caused her prolapse?

2 A. Yes, absolutely, that's my opinion, it
3 did.

4 Q. And your opinion is it contributed to
5 some extent; you just can't say to what extent,
6 right?

7 A. I think it's a significant issue in
8 this particular patient, yes.

9 Q. Do you know for how long she had been
10 lifting whatever she was lifting and doing
11 whatever activity she had been doing?

12 A. She's actually been having a history
13 of lifting for quite some time, even preceding
14 her presentation in 2008. When you look at her
15 claims of her disability application, depending
16 upon the job portion that she was doing, she was
17 lifting heavier objects when she was at Justin
18 Boots and also lifting heavier objects when she
19 was in the preceding employment, I think, at
20 Ozark Village, I believe it is, at least based on
21 how she has indicated on her disability
22 application.

23 Q. Would you agree with me that, from
24 Ethicon's perspective, it was foreseeable that

1 someone like Connie Schubert with her background
2 and history and her level of prolapse would have
3 a Prolift put into her body?

4 MS. JONES: Object to the form.

5 THE WITNESS: Do I think Ethicon knew
6 she was going to have a Prolift?

7 BY MR. SLATER:

8 Q. -- what I asked you.

9 A. I'm sorry. That's what I thought --

10 Q. Do you agree with -- do you agree with
11 me that it was foreseeable to Ethicon that a
12 woman with Connie Schubert's profile, her medical
13 history, her background, her occupational
14 history, would be somebody who would have a
15 Prolift put in her body?

16 A. Yes.

17 Q. And you would agree with me,
18 therefore, that Ethicon was obligated to design
19 the Prolift to be effective and safe in a woman
20 with Connie Schubert's profile, correct?

21 MS. JONES: Object to the form.

22 THE WITNESS: I think that, yeah, it
23 was -- it was ideally their -- or the company was
24 trying -- was responsible for trying to design a

1 repair that would be able to treat prolapse in a
2 particular patient like this.

3 BY MR. SLATER:

4 Q. One of the things that Ethicon did was
5 they claimed that the Prolift would provide a
6 more durable repair than a native tissue repair,
7 right?

8 A. Yes.

9 Q. After Connie Schubert had the Prolift
10 put in her body, she eventually went back to
11 work, right?

12 A. Yes.

13 Q. Do you know how much activity she did
14 at work once she went back to work after the
15 Prolift?

16 A. I know based on her employment records
17 the number of hours that she was working during
18 that time period. I cannot specify whether
19 she -- what she actually did during each of those
20 different work days.

21 Q. Therefore, you would not --

22 A. Oh, may I --

23 Q. Go ahead.

24 A. I'm sorry. I will say, though, that

1 based on the medical record she was doing a level
2 of physical activity that her physician felt was
3 of concern and that that could contribute to
4 problems with less-than-optimal results from the
5 Prolift or with recurrent prolapse, as the
6 physician specifically wrote a letter to her
7 employer saying that she needed to have a
8 reduction in her activity or physical demands at
9 work. So, clearly --

10 Q. At the time Dr. Robert --

11 A. Go ahead. Sorry.

12 Q. At the time Dr. Roberts wrote that
13 note, you don't know what Connie Schubert was
14 actually doing at work at that time period,
15 right?

16 A. No.

17 Q. It was foreseeable to Ethicon that a
18 woman like Connie Schubert would have a Prolift
19 put in her body and then would eventually go back
20 to work and attempt to perform her functions at
21 work, right?

22 MS. JONES: Object to the form.

23 THE WITNESS: I would expect that
24 Ethicon would know that the patient would return

1 to her activities after the surgery. At which
2 point after the surgery she would return and to
3 what level of activities I don't think that
4 Ethicon could know that.

5 BY MR. SLATER:

6 Q. Well, Ethicon certainly marketed the
7 Prolift as a device that would provide a durable
8 repair and let women like Connie Schubert go back
9 to work and be active and return to their active
10 lifestyle, right?

11 A. They marketed it as allowing patients
12 to return to normal activities, yes, and to be a
13 repair that would allow them to do that.

14 Q. There's no -- well, rephrase.

15 You're not forming the opinion to a
16 reasonable degree of medical probability that any
17 particular activity performed by Connie Schubert
18 after the Prolift surgery caused her recurrence
19 of prolapse, are you?

20 A. Not a particular. I think it's
21 probably a cumulation of multiple things, not a
22 single thing.

23 Q. And among the things that caused or
24 contributed to her recurrence was the -- most

1 likely the contraction of the Prolift mesh.

2 That's one of the contributing factors, correct?

3 A. No, I'm not saying that that's the
4 most likely. I mean, the whole point is, even if
5 the patient had not had a Prolift performed and
6 had had a native tissue repair, she still is at a
7 risk of failing from that procedure. So you
8 can't sit there and say that just because she
9 failed and she had a Prolift, that Prolift was
10 the contributing factor or the cause because the
11 same thing could have happened if she had had
12 some other different type of repair. So I don't
13 think that you can point to just that Prolift in
14 and of itself caused the patient to develop the
15 issue of recurrence.

16 Q. So if I understand correctly, you're
17 not giving an opinion as to what caused Connie
18 Schubert's recurrence, correct?

19 A. That's not what I said. I said that
20 there are contributing -- a group of contributing
21 factors that would probably be associated with
22 her developing her recurrence of her prolapse,
23 and some of those factors would be independent of
24 what surgery or not the patient actually

1 experienced. Some of the factors may be
2 surgically dependent.

3 Q. When you say "surgically dependent,"
4 you mean related to the Prolift, correct?

5 A. Yes.

6 Q. Connie Schubert has complained
7 consistently of painful sexual intercourse and in
8 fact had to stop attempting to have sexual
9 intercourse due to pain, correct?

10 A. That's what the record indicates, yes.
11 Sorry. You're gone again. You're gone.

12 Q. Oh, sorry. Am I back?

13 A. Yes.

14 Q. Okay. And certainly that complaint
15 and those symptoms were caused at least in part
16 by the Prolift and then ultimately the Prolift+M,
17 correct?

18 MS. JONES: Object to the form.

19 THE WITNESS: I think that the Prolift
20 and the Prolift+M could be a contributing
21 component to her current dyspareunia or her
22 postoperative dyspareunia. I don't know that
23 they are necessarily the major or the only factor
24 associated with it -- well, actually I feel

1 pretty -- I feel quite comfortable that they are
2 not the only aspect of what's going on.

3 BY MR. SLATER:

4 Q. Well, certainly they are contributing
5 factors, correct?

6 A. The Prolift and the Prolift+M, yes,
7 are probably contributing factors, yes, but not
8 necessarily the only contributing or the majority
9 contributing factor.

10 Q. What are the other contributing
11 factors in your opinion along with the Prolift
12 and Prolift+M?

13 A. I think that part of the difficulty in
14 this patient with symptoms of dyspareunia is that
15 the prolapse in and of itself can be associated
16 with dyspareunia and the patient did have initial
17 prolapse, she did develop recurrent prolapse,
18 and, although we don't understand exactly why,
19 there is association of dyspareunia in those
20 patients even when they are treated regardless of
21 which method.

22 She has been on theoretically vaginal
23 estrogen to try to improve the quality of her
24 tissue. There are comments in the medical

1 records sort of plus and minus regarding whether
2 or not the tissue is more hypoestrogenic or
3 thinner based on estrogen state.

4 She has had comments in the medical
5 literature regarding tenderness that she
6 experiences at the vaginal introitus that is
7 potentially related to scar tissue that is yes or
8 no associated with the Prolift since the Prolift
9 isn't any longer in that particular area, and
10 certainly even after a native tissue repair you
11 can have that type of introital dyspareunia.

12 More recently she has been seen by
13 Dr. Wall who, in examining her back in June of
14 2013, noted that there was some constriction at
15 the apex of the vagina, as we discussed
16 previously, that could be a contributing factor.
17 She also was noted to have tenderness along her
18 bilateral levator muscle. So what we talked
19 about before of the levator myalgia, et cetera,
20 that can be contributing factors to dyspareunia.
21 So I think there are multiple different issues.

22 Q. What you just listed for me, that
23 combination of issues you would say contributed
24 to some extent to the dyspareunia that she has

1 complained of since the surgery? Do I understand
2 correctly?

3 A. Yes. I think even some of her
4 underlying orthopedic issues can be contributory
5 to patients -- oh, you can put your arms up, but,
6 unfortunately, we see it every day, even in
7 patients who have never had Prolift surgeries or
8 Prolift+M surgeries. So even orthopedic issues
9 can contribute to this type of problem and
10 dyspareunia in patients just because it triggers
11 the levator myalgias.

12 Q. Okay. I'm not asking for theoretical
13 possibilities, though. So you gave me a list
14 before, before you started talking about
15 orthopedic injuries. Did you hold the opinion to
16 a reasonable degree of medical probability that
17 each of those factors actually contributed to the
18 dyspareunia? You listed them: the Prolift, the
19 Prolift+M, pelvic organ prolapse, tissue quality,
20 scar tissue. You listed all those things. Is it
21 your opinion to a reasonable degree of medical
22 probability that those factors combined to all
23 contribute to her having the dyspareunia?

24 A. Yes.

1 Q. You don't hold the opinion to a
2 reasonable degree of medical probability that
3 there is any orthopedic issue contributing to
4 dyspareunia in Connie Schubert, correct?

5 A. There could be. I'm just saying --

6 Q. I'm not asking you what could be.
7 That's not my question. My question is very
8 direct. You don't hold the opinion to a
9 reasonable degree of medical probability that
10 Connie Schubert has an orthopedic issue that's
11 causing her to have -- or contributing to her
12 having dyspareunia, are you?

13 A. I can't say that that is an absolute
14 certainty, no.

15 Q. You're not forming that opinion,
16 correct?

17 A. I mean, I think I've given you my
18 opinion of what I think. I think it's a
19 contributing factor. I can't tell you that it is
20 absolutely a contributing factor.

21 You have to understand that the problem is
22 with patients that we see, patients can have all
23 of these types of complaints, they can have all
24 of these types of findings on exam, they can

1 never have had a prolapse surgery, they can never
2 have had any type of mesh placed, and yet still
3 have these. So the body doesn't tell us this
4 is -- this is, you know, 10% due to this and 30%
5 due to that and 5% due to that. You have a group
6 of contributing factors. You try to address each
7 of those individual factors, and as you remove
8 each of those individual factors from the
9 differential or the contributing list, if the
10 patient's symptoms alternatively then resolve, it
11 gives you sort of de facto data or evidence to
12 support perhaps that that was the primary cause.

13 Q. That analysis you have not performed
14 in this case, correct?

15 A. In her case, no. I've relied on the
16 analysis that's present in the chart based on
17 Dr. Wall's comments and also based on the
18 disability examination she had.

19 Q. You have not examined Connie Schubert,
20 correct?

21 A. Correct.

22 Q. You would agree with me that if you
23 had examined her that may have provided you
24 important information to help support your

1 opinions or inform your opinions, correct?

2 A. If I had examined her, that might be
3 part of it, yes.

4 Q. When you actually treat patients and
5 form opinions about what's happening with your
6 own patients, you actually examine them, correct?

7 A. Yes.

8 Q. You wouldn't diagnose your own patient
9 without examining your own patient, would you?

10 A. I will sometimes make a presumptive
11 diagnosis without an examination, yes.

12 Q. And then you would examine and do
13 testing to decide whether your presumptive
14 diagnosis was correct or not, right?

15 A. I might if I thought that that was
16 indicated.

17 Q. When you actually treat patients,
18 Dr. Horbach, you examine them.

19 A. Not always.

20 Q. You speak to them.

21 A. I don't --

22 Q. You evaluate them -- please let me
23 finish. When you examine -- rephrase.

24 When you treat your own patients, you base

1 your treatment on meeting with the patient,
2 speaking to the patient and examining the
3 patient, correct?

4 A. Evaluating a patient and determining
5 the cause for symptoms or problems does not
6 always require you to do a physical exam on the
7 patient.

8 Q. Well, in the case of Connie Schubert,
9 with somebody like her, where you're trying to
10 figure out what's the cause of her issues, you
11 would need to examine a patient like that if they
12 came to your office, right?

13 A. Yes, I would.

14 Q. Connie Schubert did not have a native
15 tissue repair, correct?

16 A. Correct. She had a little bit of work
17 done along the, sounds like, along the distal
18 portion of the posterior vaginal wall that was
19 just plication.

20 Q. Are you talking about during which
21 operation?

22 A. Well, she had anterior wall plication
23 during operation number 2 with Dr. Roberts, and
24 it was my recollection that he did some degree at

1 the first operation, but let me review my notes.

2 No, I'm sorry, in that particular
3 procedure, it just looks as if he put the
4 posterior Prolift in.

5 Q. Would you agree with me Connie
6 Schubert did not have a native tissue repair,
7 correct?

8 A. Not at the first surgery, no.

9 Q. Rephrase. Before you mentioned, you
10 know, some things can happen even if you don't
11 have a Prolift. Well, Connie Schubert had a
12 Prolift, so we should be evaluating what happened
13 to her in the setting of her having a Prolift and
14 then a Prolift+M, correct?

15 MS. JONES: Object to the form.

16 THE WITNESS: Yeah, that's what I am
17 trying to do. But what I'm saying is that you
18 can't directly link a causative aspect for a
19 symptom or problem to a particular treatment if
20 that symptom or problem can happen in the absence
21 of that particular treatment.

22 BY MR. SLATER:

23 Q. The Prolift is a procedure, correct?

24 A. Yes.

1 Q. Connie Schubert underwent a Prolift
2 procedure, correct?

3 A. Yes.

4 Q. That procedure encompassed from the
5 very first incision through all the dissections,
6 the placement of the mesh, the insertion and the
7 removal of the cannulas and the guides, right
8 down to closing all of the incisions at the end,
9 that is the Prolift procedure from beginning to
10 end, correct?

11 A. Yes.

12 Q. So whatever resulted from that
13 procedure resulted from the Prolift procedure,
14 correct?

15 MS. JONES: Object to the form.

16 THE WITNESS: Yeah, I mean, I don't
17 know that I can answer that yes or no.

18 BY MR. SLATER:

19 Q. Well, here's the thing. Connie
20 Schubert had a Prolift procedure. That's what
21 was done to her body. You can agree to that,
22 right?

23 A. Yes, but I can't tell you that it in
24 itself is the only reason that the patient

1 developed these symptoms.

2 Q. Didn't ask you that. You're being a
3 little defensive. I never asked you that.

4 A. No, then I may have misunderstood.

5 Q. Yeah. I'm starting very small.

6 Connie Schubert had a Prolift procedure, correct?

7 A. Yes.

8 Q. To the extent that any complications
9 resulted from the procedure that she had, by
10 definition, they resulted from the Prolift
11 procedure, correct?

12 A. No. That's why we just had the
13 discussion.

14 Q. You didn't listen to my question.
15 Here's my question. To the extent a complication
16 resulted from the procedure that she had on
17 December 8, 2008, the extent that any
18 complication resulted from that procedure, by
19 definition, that complication resulted from the
20 Prolift procedure because that's the procedure
21 she had, correct?

22 MS. JONES: Object to form.

23 THE WITNESS: If I understand that
24 question, it is -- if she has a

1 procedure-dependent complication, then the
2 Prolift was the cause of that since that's the
3 procedure she had. Is that my -- is that
4 correct?

5 BY MR. SLATER:

6 Q. Yes.

7 A. Then, yes, I'd answer yes.

8 Q. Yes. Okay. She did not have any
9 other procedure performed on December 8. She had
10 a Prolift procedure, correct?

11 A. Yes.

12 Q. So even though it may be that
13 alternative procedures that were not performed
14 could have lead to certain similar complications,
15 it would be speculative to say those procedures
16 would have had the same result because she didn't
17 have any alternative procedure, correct?

18 A. It is speculation, yes, but it's also
19 medically --

20 Q. And the same --

21 MS. JONES: Let her finish the answer.

22 BY MR. SLATER:

23 Q. I didn't mean to interrupt you. I'm
24 sorry. I thought you had answered.

1 A. But it's also medically and clinically
2 a reality of what we see in patients that we
3 treat. So it's not just pulling something out of
4 the air.

5 Q. Well, move to strike from "but"
6 forward.

7 Just to be very clear, it would be
8 speculative to say, well, if Connie Schubert had
9 a different procedure, here's what would have
10 happened, right?

11 A. Yes. It's speculative based on my
12 clinical experience and judgment, yes.

13 Q. The things I just asked you about the
14 Prolift procedure would apply to the Prolift+M
15 procedure in 2009, correct?

16 A. I would expect, yes.

17 Q. Is there a specific orthopedic injury
18 or condition that you would say, as you sit here
19 now, that that condition to a reasonable degree
20 of medical probability is a cause of her, Connie
21 Schubert's, dyspareunia since the Prolift
22 surgery?

23 A. I think that there is a reasonable
24 degree of medical certainty that it can be a

1 cumulative effect of some of the orthopedic
2 issues that has been -- have been going on in the
3 past. I've certainly seen patients who develop
4 solely an orthopedic issue where they have a
5 fractured ankle and they develop dyspareunia
6 secondary to their fractured ankle. I mean,
7 you -- that is something that we see in clinical
8 practice, yes, and this patient has had --

9 Q. Did Connie --

10 A. Go ahead.

11 Q. Did Connie Schubert have a fractured
12 ankle?

13 A. No, but she certainly has a number of
14 other orthopedic issues that are going on.

15 Q. Here's the question. Do I understand
16 you correctly to be saying -- Connie Schubert has
17 some orthopedic issues in her background. It's
18 possible that an orthopedic issue could be
19 contributing to her post-Prolift condition in
20 terms of her dyspareunia, her pain, her
21 discomfort in her pelvis. You're not saying to a
22 reasonable degree of medical probability that it
23 is; you're just saying that it could be. Are
24 we -- do I understand you?

1 A. I think that that's a fair statement.

2 Q. Now, coming back to Connie
3 Schubert's -- actually let me -- let's go back to
4 your reliance list, Exhibit 4. You have a list
5 of medical literature that goes on for several
6 pages.

7 A. Mm-hmm.

8 Q. Why did you list that medical
9 literature?

10 A. As we had said at the beginning of
11 looking at this list, these are simply -- these
12 are information or articles that were sent to me
13 as part of the documentation related to this
14 case.

15 I have, in addition, articles that I have
16 potentially read or articles that I've read over
17 the last year, year and a half involved in the
18 Prolift litigation, especially since I just sat
19 down and took my board exams in June. So there's
20 a huge amount of literature that I've read or
21 reviewed that I use as a background clinically to
22 make my decision and my conclusions about this
23 particular case. So this is simply the
24 information that was sent to me via from the --

1 regarding the case and from the attorney's
2 office.

3 Q. The list of literature on this
4 document is literature that was sent to you by
5 Ethicon's attorneys, correct?

6 A. Yes.

7 Q. Did you read all these articles in
8 their entirety?

9 A. I would say pretty much all of these
10 articles in their entirety I have read, yes, at
11 one point or another in the last year and a half.
12 When we went through this --

13 Q. Are you relying --

14 A. Sorry.

15 Q. Go ahead. I didn't mean to interrupt
16 you. There was a delay.

17 A. When we went through this I think
18 yesterday, I marked a couple notes on ones that I
19 couldn't recall absolutely for sure that I had
20 read in its entirety, but that was probably, you
21 know, half a dozen or ten of these particular
22 papers.

23 Q. You're not telling me that every one
24 of the articles here on this list supports your

1 opinions in this case, are you?

2 A. I'm not saying that they support, but
3 they are a part of what I used to generate my
4 opinion. Some of the papers may not support my
5 opinion. They may have data that suggests that
6 my opinion is -- is different. But then I have
7 to evaluate the data to determine whether I think
8 it is -- it accurately -- that it is a reliable
9 study and reliable data for me to use in making a
10 decision.

11 So you're going to look at supportive
12 evidence and you're going to look at evidence
13 that's contrary, and you're going to weigh the
14 pros and cons of those evidence to create an
15 overall opinion relative to this particular
16 patient and the Prolift.

17 Q. There is literature on this list that
18 would be irrelevant to your opinions in this
19 case, correct?

20 A. I'm not sure that is the case per se.
21 I would have to go through each of them to
22 determine. I'm not sure which ones you're
23 referring to.

24 Q. You're not relying on literature with

1 regard to SUI mesh or TVT mesh to form your
2 opinions in this case, are you?

3 A. Yes.

4 Q. You believe that the characteristics
5 and the performance of the TVT meshes is relevant
6 to determining the safety or efficacy of the
7 Prolift?

8 A. Yes, for TVT and TOT.

9 Q. Do you know whether or not Ethicon
10 ever told the FDA whether or not Ethicon thinks
11 that the TVT is something that should be
12 considered in determining the safety and efficacy
13 of the Prolift?

14 A. I do not know that.

15 Q. If Ethicon told the FDA that the TVT
16 devices should not be considered in evaluating
17 the safety and efficacy of the Prolift, would you
18 defer to that statement by Ethicon to the FDA?

19 MS. JONES: Object to the form.

20 THE WITNESS: I think that it -- it
21 doesn't necessarily -- it doesn't impact my
22 clinical opinion regarding the relevance of the
23 TVT and TVT data to the Prolift.

24 BY MR. SLATER:

1 Q. Would you expect that Ethicon's
2 internal medical affairs doctors and the
3 scientists that work there have a significantly
4 larger body of knowledge and insight into the
5 properties and the safety and efficacy of the
6 Prolift and the Prolift+M than you do?

7 MS. JONES: Object to the form.

8 THE WITNESS: I can't answer that one
9 way or the other. I -- you know, they may, they
10 may not. They don't do Prolifts, so they may or
11 may not have the same ideas.

12 BY MR. SLATER:

13 Q. You don't know -- do you know --
14 rephrase.

15 Do you know whether anybody working in
16 Ethicon Medical Affairs had actually performed
17 Prolift surgery as physicians?

18 A. I don't know for sure, although there
19 was a reference that David Robinson had made in
20 something I read that seemed to imply that he may
21 have.

22 Q. Would you expect that Ethicon has a
23 greater body of knowledge about the safety and
24 efficacy of the Prolift by virtue of the fact

1 that they have access to doctors all over the
2 world and they have been studying this device
3 internally and looking at data on a day-to-day
4 basis? Let me ask the question cleaner. I got a
5 little lost.

6 Would you agree that Ethicon likely has a
7 greater body of knowledge regarding the safety
8 and efficacy of the Prolift and Prolift+M than
9 you do?

10 A. They probably have more information
11 about it, yes.

12 Q. Is there any -- well, let me ask you
13 this. You said that in addition to the medical
14 literature listed here that you've reviewed other
15 medical literature, correct?

16 A. Yes.

17 Q. You've obviously reviewed other
18 medical literature other than what's on this
19 list.

20 A. Yes.

21 Q. What I need to understand is -- what I
22 need to understand is what medical literature
23 you're specifically going to point to if we go to
24 trial and say this is the literature that I'm

1 relying on for my opinions. Is there any
2 particular article as we sit here now you can
3 point to and say, you know, this article and that
4 article I'm specifically relying on to support my
5 opinions, so I understand when I go to trial what
6 to expect for you to talk about?

7 A. At this particular time I think it's
8 more of the global information. I think there
9 are individual articles that I may use to support
10 my opinion, and some of those are, you know, here
11 in my stack or pulled last night, et cetera. So
12 that they are clearly not on your list, but
13 you're welcome to have the list.

14 Q. Well, here's what I want to know. You
15 have a pile of articles there that --

16 A. I actually have --

17 Q. -- that's in addition to what's on
18 this list?

19 A. I have some that are in addition to
20 that list. I mean, I have a huge, couple
21 notebooks, but some of that is already on this
22 list and some of it isn't.

23 Q. Well, here's what I need to know.
24 Which articles do you believe are the ones that

1 support your opinions -- and I'm talking about
2 the articles that you would rely on to say to me
3 these are the articles I rely on for my opinions
4 in this case?

5 A. There are probably specific articles
6 that I would cite and there are articles -- I
7 mean, I'm using all of this information to rely
8 on my opinion. If there was a -- if there is a
9 specific article, I'm going to say, according to
10 the study of Dr. X, that this is the data that's
11 there -- is that what you're asking for, that
12 type of article?

13 Q. Right. I want to know is there a
14 specific article or articles that you can tell me
15 now, look, this article clearly supports my
16 opinions, I'm going to rely on this?

17 A. Yes, I have --

18 THE REPORTER: One at a time, please.

19 MS. JONES: One at a time.

20 THE WITNESS: I have, yes, I do have
21 some of those articles, and I -- you know, you
22 can have any of them now. Otherwise, if you
23 would like, I can go back through each of the
24 individual articles that I have with me to say --

1 and provide you with a list that says these are
2 ones that I will probably be citing during my
3 testimony.

4 BY MR. SLATER:

5 Q. I don't want you to go back because
6 this trial is in one month and today's the day
7 for me to talk to you. So, to the extent you
8 can, tell me right now, these are the key
9 articles that I'm going to rely on for my
10 opinions, or, if you're not prepared to do that,
11 you can tell me you can't do it. I just need to
12 know. I don't want some supplemental list. I
13 have a lot of work to do between now and trial,
14 with all due respect, and today is my day to
15 analyze you as an expert and then move on to
16 other witnesses.

17 A. All right. So, in that case, we can
18 sit there and go through the notebook and we can
19 go article by article so that you'll have the
20 information today since you don't want a
21 supplemental report.

22 Q. Let me just tell you something,
23 Doctor. Sit up for a second, please. Let me
24 explain to you what we're doing here. This is a

1 very, very formal and important proceeding. So
2 understand something. You're testifying under --
3 you don't have to look at the attorney. You look
4 at me. You don't --

5 MS. JONES: Wait, wait, wait.
6 Counsel --

7 MR. SLATER: No, I'm going to talk.

8 BY MR. SLATER:

9 Q. You're not going to now look at me and
10 you're not going to say to me in a snide way,
11 well, I'll read the whole notebook to you of at
12 least a thousand articles. Because let me tell
13 you something. That's not how it works in any
14 court in this country. Okay? I asked you a
15 direct question, which any expert would be
16 expected to be able to answer. Okay? And I
17 can't get a direct answer. And if you think
18 you're going to read to me a thousand article
19 titles and it's going to hurt me, you'll be
20 coming back for this deposition to continue in a
21 couple days, probably Saturday, okay, because I'm
22 going to finish your deposition. I'm not going
23 to leave it open. I'm not going to get a
24 supplemental report. You're not going to rethink

1 it and figure out what you want to say. Today is
2 the deposition.

3 I spent a lot of time preparing for this.
4 Mr. Overby flew in from Missouri. He expects the
5 same type of concise testimony. So we're not
6 going to play games and I'm not going to be
7 spited and have, well, if you ask for it, here's
8 what you get. I would ask for a professional
9 answer.

10 You're an expert witness being paid a lot
11 of money by a big corporation, and this is not a
12 surprising question. Either you're ready to
13 answer it or you're not. So let's try to cut to
14 the chase.

15 MS. JONES: Counsel --

16 BY MR. SLATER:

17 Q. Counsel has asked me to get her out of
18 here by a certain point.

19 MS. JONES: Counsel --

20 BY MR. SLATER:

21 Q. So let's not keep things going for
22 more than it needs to.

23 MS. JONES: And let's not have any
24 more diatribes and tirades by plaintiff's counsel

1 in this case. She has tried to answer your
2 questions. The witness has tried to answer your
3 questions. She has offered to give you a list
4 here. She has got all the materials here. We've
5 given you a list of the materials that she has
6 reviewed. She is trying to answer it.

7 So, please, let's have a little common
8 courtesy, and she will go through and give you
9 the list by going through the notebooks and the
10 materials that she has here. Okay?

11 BY MR. SLATER:

12 Q. Tell me which articles -- tell me
13 which articles, please, are most significant to
14 you in supporting the opinions in this case.

15 A. There are a group of articles that are
16 part of the randomized trials that have occurred
17 subsequent to the launch of Prolift. And I can
18 give -- sorry. I'm trying to remember where I
19 have that specific list.

20 There is also -- but I will give you the
21 names of the articles here in a second. Some of
22 those are on here; some of them aren't. There
23 is, I mean, the CARE trial that is part of the
24 NIH's Pelvic Floor Treatment Network at the

1 two-year data and the seven-year data. The, you
2 know, Altman, New England Journal of Medicine
3 article that was published fairly recently.
4 There is an article that was published via Matt
5 Barber on the OPTIMAL study and the sister study
6 that is information also about use of pain scales
7 in evaluating patients after pelvic
8 reconstructive surgery. That's Matt Barber's
9 article from Female Pelvic Medicine in July or,
10 sorry, August of 2012.

11 There is -- you know, again, I'm trying to
12 remember what's on this list and what's not on
13 this list. There is the most recent Cochran
14 review. There is the SGS review for the use of
15 mesh. There is the, I think, 11-year data on
16 TVTs is already present for here. There are
17 articles -- just trying to remember...

18 You know, you have to bear with me to some
19 extent too since some things, especially when
20 there was a repetitive forwarding of articles, I
21 tried to combine to be able to have one notebook
22 instead of four different notebooks. So some of
23 these have marks and some of them don't, even
24 though they are articles that were possibly in

1 this list. I may not recall off the top of my
2 head whether those are on in list -- this one is
3 already an exhibit -- because of the fact that
4 the list is a combination of things.

5 MS. JONES: Why don't you -- I think
6 what he's asking for is just the title or the
7 authors of --

8 THE WITNESS: The bulk of them?

9 MS. JONES: -- what you believe are
10 the more important studies. Why don't you just
11 flip through there --

12 Is that acceptable to you?

13 THE WITNESS: I think that --

14 MR. SLATER: I want to know which of
15 the key articles that Dr. Horbach intends to rely
16 on at trial to support her opinions. There's a
17 list -- I obviously don't expect her to talk
18 about 50 or a hundred articles. I need to know
19 which are the ones she actually intends to rely
20 on.

21 THE WITNESS: I think you and I have a
22 different definition -- no, I think you and I
23 have a different definition of what it means to
24 rely on them. That's why there is a confusion.

1 The article that is from Obstetrics and
2 Gynecology in 2011 for the Withagen article,
3 Trocarguided Mesh Compared to Conventional
4 Repairs, the article that is by Lowe from
5 Abdominal Sacrocolpopexies and Sacrospinous
6 Ligament Comparison. The Hiltunen articles --
7 and there's three of them -- on their studies
8 about at the short-term interval for randomized
9 trial, the three-year data, I believe, and then a
10 subsequent article that came out by them in --
11 there's 2007, 2008 and 2010.

12 The Carey article, Vaginal Repair with
13 Mesh versus colporrhaphy; the Lopez article of
14 Transvaginal Polypropylene Mesh versus
15 Sacrocolpopexy. Those are all articles that I
16 would potentially be looking at.

17 The -- there was one -- the VAMP trial by
18 Iglesia that was published in 2010. There was an
19 article in Ultrasound -- let me see here --
20 talking about mesh contraction in Gynecologic
21 Ultrasound.

22 BY MR. SLATER:

23 Q. -- article?

24 A. I'm sorry? Yes, I'm trying to give

1 you --

2 Q. -- article?

3 MS. JONES: Can't hear you.

4 THE WITNESS: Yeah. I'm sorry. I
5 can't -- you keep cutting out, but there is an
6 article --

7 BY MR. SLATER:

8 Q. I asked you if that's the Velemir
9 article.

10 A. Yes, I think it's that. I'm terrible
11 with names, so I will assume that that's the same
12 one, but it talks about mesh retraction in the
13 Ultrasound article.

14 Q. The other one is Jacquetin, et al.,
15 right?

16 A. Probably.

17 MR. SLATER: Jacquetin, which is
18 J-A-C-Q-U-E-T-I-N.

19 THE WITNESS: He's probably better at
20 pronunciation of names than I am.

21 That covers this particular notebook, I
22 think. Give me a second.

23 THE REPORTER: If we're on the record,
24 I need to hear you.

1 THE WITNESS: I'm sorry. I was just
2 talking to myself.

3 THE REPORTER: I know.

4 MS. JONES: Just so we're clear --

5 THE WITNESS: Do you want --

6 THE REPORTER: One at a time.

7 MS. JONES: If you think they are
8 important articles to you, even though they are
9 on the list, go ahead and give him the titles of
10 them again or at least the authors.

11 THE WITNESS: All right. This is the
12 article with Mark Walters, Anne Weber, Barber,
13 et cetera, the Reanalysis of the Three Randomized
14 Trials or the Three Randomized Techniques for
15 Anterior Colporrhaphy; the Ridgeway article
16 regarding -- from the American Journal of
17 Obstetrics and Gynecology in 2008 regarding
18 Excision of Mesh; the article by Matt Barber
19 regarding Defining Success after Surgery for
20 Pelvic Organ Prolapse.

21 We talked about -- there was -- trying to
22 remember who the article is. There is an article
23 on Uterosacral Ligament Suspensions and the
24 Associated Ureteral Injury Rates that are as high

1 as the 11%, and I am trying to remember which
2 institution that that came out of.

3 The Maher article about sacrocolpopexy
4 and -- Sacrocolpopexy versus Sacrospinous
5 Ligament Fixation in 2004; the Diwadkar -- which
6 I can't pronounce -- article on Complications and
7 Re-Operations.

8 I would be using also the articles on
9 Transvaginal Mesh, both the French and the U.S.
10 series that have been published short-term as
11 well as the long-term since you're wanting to be
12 specific about those as well as the combination
13 one. Would be from the John DeLancey, Dee
14 Fenner's article back in 2008, American Journal
15 of Ob/Gyn regarding Complications Following
16 Operations for Vaginal Mesh Kits.

17 The article that we published with Matt
18 Aungst as the primary author about Stress
19 Incontinence and Pelvic Symptoms -- Pelvic Muscle
20 Symptoms Postoperatively; the article by Milani
21 about Outcomes and Predictors of Failure after
22 Trocar Placement; the Nguyen article on
23 Perioperative Complications that is from
24 Obstetrics and Gynecology in 2012.

1 There is information regarding urinary
2 tract -- well, the Nerve Entrapment Issues for
3 Lower Extremities. This author is Hollis. I
4 don't know that I have a date on that. We're
5 almost done.

6 The Mickey Karram article on Sexual
7 Function after Vaginal Surgery for Prolapse; the
8 Altman article on Sexual Function after
9 Trocac-Guided Repairs; the Handa article on
10 Sexual Function Before and After Sacrocolpopexy.

11 I think that is the group. Again, some of
12 them may or may not be on that list already.

13 BY MR. SLATER:

14 Q. The SGS review you talked about was
15 authored by Miles Murphy, correct?

16 A. No, that's the SGS -- well, actually
17 that's a good point. Miles Murphy's response
18 that was done by the Pelvic Surgeons Group, that
19 is one that I would use, but the one I was
20 talking about is the systematic -- the SGS's
21 systematic review that was published -- I think
22 Vivian Sung is the author, I think, on that.

23 Q. Let me ask you a question about the
24 Miles Murphy, Time to Rethink. That's not a

1 peer-reviewed article. You know that, right?

2 A. Yes, I know that.

3 Q. And you know that the Pelvic Surgeons
4 Network or whatever they called themselves was a
5 made-up name that he and Vince Lucente came up
6 with?

7 A. Yes.

8 Q. It's not considered to be a
9 peer-reviewed, scholarly article, correct?

10 A. I think -- no, it was an opinion or an
11 editorial.

12 Q. Okay. With regard to the TVM study,
13 you mentioned the three- and five-year articles,
14 correct?

15 A. I believe so. I can pull them back
16 out, if you want.

17 Q. You did not analyze, as you told me
18 earlier, whether or not the reported data was
19 accurate, correct?

20 A. No, I did not look back at the
21 original data, no.

22 Q. Do you know to what extent there were
23 errors with the POP-Q measurements in the TVM
24 studies performed in the U.S. and France?

1 A. It was my understanding that there
2 were 78 errors according to Dr. Weber's review of
3 the data.

4 Q. If there were systemic errors with the
5 POP-Q measurements and no reliable way to correct
6 them, that creates serious questions about the
7 accuracy of that data, correct?

8 MS. JONES: Object to the form.

9 THE WITNESS: I don't necessarily
10 agree with that.

11 BY MR. SLATER:

12 Q. Okay. With regard to the recurrence
13 rate reported in the TVM study, if there were
14 systemic errors and systemic lack of
15 understanding of POP-Q measurements, you could
16 not state that the recurrence data would be valid
17 or reliable, right?

18 MS. JONES: Object to the form.

19 THE WITNESS: I don't think that I
20 necessarily can agree with that statement. If
21 you look at the number of measurements that could
22 have been -- were potential during that study, if
23 you have 78 errors out of the thousands that were
24 potentially measured, given you have 90 patients

1 and you have multiple measurements, your error
2 rate is actually not particularly, you know, a
3 high percentage.

4 In addition, many of the -- when there was
5 an error, it was sent back to be queried by the
6 initial clinical investigator. If you hold the
7 same kind of -- I'm just going to stop there.

8 Q. This was followed to correct the
9 errors that were found --

10 A. I'm sorry.

11 Q. I'll ask it again. You don't know
12 what process was followed to try to correct the
13 errors in the POP-Q measurements that were
14 actually detected because the measurements were
15 found to be impossible. You don't know what was
16 done, do you.

17 A. It was my understanding that the
18 investigators were -- that the information was
19 sent back to the investigators and/or clinical
20 study sites for querying to determine whether or
21 not there was a mis-entry or whether or not that
22 information was accurate.

23 Q. The people who reviewed the data found
24 multiple entries where the data was impossible.

1 Are you aware of that?

2 A. Yes.

3 Q. The fact that the people who are
4 recording the POP-Q measurements were coming up
5 with impossible figures creates reliability
6 questions about the recurrence rates reported,
7 correct?

8 MS. JONES: Object to the form.

9 THE WITNESS: I don't agree
10 necessarily with that. I don't think that just
11 because they were --

12 BY MR. SLATER:

13 Q. Fine. You don't agree. That's fine,
14 Doctor. That's all I wanted to know.

15 A 15% mesh exposure rate is a very high
16 rate, isn't it?

17 A. 15% is a 15% rate. I mean, whether
18 you determine it high or not, if it's the
19 patient, she probably does determine it's high.
20 If it's looking at across the board, it may not
21 represent a number that is substantially higher
22 than in some other mesh procedures that are done
23 with sacrocolpopexies and certain types of mesh.
24 But it is on the higher side, yes.

1 Q. A 20% exposure rate, if that's what a
2 study showed is consistently being obtained for
3 community physicians, if there was a study that
4 said that, you would say that's unacceptably high
5 and the device shouldn't be used, right?

6 MS. JONES: Object to the form.

7 THE WITNESS: I would say that that
8 was not something -- that would not be a material
9 that I would use for -- in that particular
10 procedure -- I probably would not use with a 20%
11 erosion rate.

12 BY MR. SLATER:

13 Q. Did there come a time in your practice
14 where you -- well, let me ask you this. Take a
15 step back.

16 You said you did a hundred to two hundred
17 Prolift procedures during the time you started
18 using it through when you stopped in 2011.
19 Therefore, based on the gross number of prolapse
20 procedures you did, Prolift was actually a small
21 number of the prolapse repairs that you were
22 doing, correct?

23 A. I'm not sure that it was -- I would
24 say it's a small number. I mean, you were asking

1 me to give you estimates, and I gave them to you
2 to the best of my ability. There certainly was a
3 period of time prior to us beginning to do
4 laparoscopic sacrocolpopexies where there was a
5 bulk of the procedures that we were doing were
6 Prolift procedures, yes.

7 Q. During the time that you did the
8 Prolift, the Prolift was always less than half of
9 the prolapse procedures you were doing, correct?

10 A. If you take that entire span of time,
11 probably, yes. If you take sort of more narrowed
12 times during that time period it was probably at
13 a higher percentage.

14 Q. Over the entire time you did the
15 Prolift, it was less than 50% of the prolapse
16 procedures you were performing during that time
17 period, correct?

18 A. Again, I'm answering this to the best
19 of my ability. I can't really say whether it's
20 going to be more or less than that.

21 Q. You said you were doing several
22 hundred prolapse procedures a year and you did a
23 total of a hundred to two hundred Prolifts. I
24 understand those are estimates, but if you take

1 those numbers as being your best estimate, the
2 Prolift was a small percentage of the overall
3 prolapse procedures you were doing, correct?

4 A. We've already -- I mean, I've answered
5 that to the best of my ability.

6 Q. Am I correct?

7 A. I can't say that you're correct or
8 not. I've answered the question to the best of
9 my ability so far -- or already.

10 Q. Did there come a point where you began
11 to have concerns about the safety of the Prolift
12 and started to cut back on utilizing the Prolift?

13 A. Not for safety reasons, no.

14 Q. Why did you start to cut back on the
15 use of the Prolift?

16 A. In part because we were able to do the
17 laparoscopic procedures, but in part it was that
18 I found or that we found that there -- there was
19 a group of patients that did have a higher chance
20 of prolonged postoperative recuperation or some
21 increased problems with pain or muscular
22 dysfunction that required, let's say, physical
23 therapy postoperatively, that there was a group
24 of patients that fell into that category, and,

1 unfortunately, since I'm referred a fair number
2 of patients with sort of some type of chronic
3 pain condition, a number of my patients fall into
4 that category.

5 I also found that for certain anatomic
6 aspects of a patient's exam, the Prolift did not
7 do as well as other procedures. If I was trying
8 to get a apical support procedure as my primary
9 type of support procedure, that was the primary
10 thing I needed, then I did not feel that the
11 Prolift could give me quite as deep of an apical
12 support as what I could obtain with the
13 sacrocolpopexy. When the sacrocolpopexies were
14 open procedures, then the pro/con, risk/benefit
15 still sometimes went in the favor of the Prolift.
16 When the sacrocolpopexies became laparoscopic
17 procedures, sometimes the pro/con for apical
18 support shifted into the direction of the
19 sacrocolpopexy.

20 Q. You said you found that some patients
21 had a higher risk to develop pain or chronic pain
22 after a Prolift procedure, correct?

23 A. More I said that they have a higher
24 risk of having pain or increased pain

1 postoperatively after the procedure that --

2 Q. Which patients?

3 A. Fibromyalgia definitely were at, I
4 think, increased risk. Patients who had
5 preoperative levator myalgia that was associated
6 perhaps with biomechanical abnormalities and
7 structural abnormalities from, again, the
8 orthopedic components.

9 I don't think I -- I don't really treat a
10 lot of patients at this point with interstitial
11 cystitis, so that doesn't really apply for me. I
12 think it was more the people with biomechanical
13 abnormalities history. I mean, I examine each of
14 my patients to look at alignment issues,
15 symmetry, and if those patients had significant
16 asymmetry or they had preoperative muscular
17 abnormalities already, then I would counsel them
18 that they may have more difficulty
19 postoperatively or they may require a longer
20 recuperation or they may require physical therapy
21 treatment, just like I would tell them even for
22 sacrocolpopexy that would be the case. But I
23 think it probably was a little bit more likely to
24 happen after Prolift in those patients.

1 Q. Did you -- I think what I'm hearing,
2 but tell me if I'm correct -- you came to
3 conclude over time that, if a patient had a
4 pre-existing chronic pain condition, that person
5 would have a higher risk of developing pain or
6 prolonged pain after a Prolift?

7 A. Yes.

8 Q. And you felt that it was better to
9 avoid using a Prolift in those patients, correct?

10 A. I mean, I'd counsel the patient
11 regarding the pros and cons. Sometimes we would
12 still proceed with a Prolift because there were
13 other reasons that we would do it, but other
14 times we would not choose to do a Prolift. We
15 would choose another round.

16 Q. If the patient could safely undergo an
17 alternative procedure and the patient had a
18 chronic pain condition of some sort, your
19 counseling would have been we shouldn't do a
20 Prolift, we should do the other procedure,
21 correct?

22 A. That's certainly a possibility, yes,
23 that could -- I would have potentially counseled
24 the patient that this is probably a procedure

1 that's going to result in more issues
2 postoperatively than if we do it this way, even
3 though the other procedure doesn't necessarily
4 eliminate the possibility of those problems as
5 well.

6 Q. You're just trying to reduce the risk
7 as best you can for those patients, and your
8 counseling was you're better off not doing the
9 Prolift because it increases your risk more than
10 these other procedures. Fair statement?

11 A. Correct. And sometimes I would not
12 include Prolift as an option in my counseling
13 just like I wouldn't include sacrocolpopexy as an
14 option in my counseling for some patients based
15 on their underlying history and anatomy and risk
16 factors, et cetera.

17 Q. You said that patients -- well,
18 rephrase -- you said some patients -- well,
19 rephrase.

20 In certain anatomic issues you didn't
21 think the Prolift did as well, and one of those
22 was if apical support was needed, correct?

23 A. Well, apical support in a specific
24 situation where the patient has a uterus in

1 place, she has a retroverted uterus, a shorter
2 anterior wall compared to posterior vaginal wall
3 length, then I didn't always find that I got as
4 well-supported apex at the level of the depth
5 that I wanted if I went to a Prolift.

6 Q. Looking at Exhibit 4 again, let's go
7 to the list on -- the pages aren't numbered, but
8 after the list of literature, it then says,
9 "Pleadings." Were those pleadings of
10 significance to you or was it just something you
11 were provided and you put -- and you just put on
12 the list?

13 A. Let me see if I can get to that point.
14 Okay. In the interrogatories that I reviewed I
15 don't think that there was anything that I relied
16 on specifically in my opinions. As I recall --

17 Q. The next section says -- I'm sorry. I
18 didn't mean to interrupt you.

19 A. That's okay. As I recall, they were
20 fairly brief answers.

21 Q. The last section on this sheet says
22 "Other." Do you see that?

23 A. Yes.

24 Q. These would be materials that were

1 provided by the Ethicon attorneys to you,
2 correct?

3 A. Yes.

4 Q. Did you read all these materials and
5 watch all the videos?

6 A. I saw most of the videos. As far as I
7 recall, I read all of these different other
8 issues, emails, all of the professional education
9 materials, some of the FDA information going back
10 and forth, yes, I think most all of the rest of
11 it I read.

12 Q. You've referred a couple times to
13 emails. To the extent you're referring to
14 emails, they would be within these documents in
15 the list of, quote/unquote, Other?

16 A. Yes.

17 Q. In terms of whether or not the IFU
18 adequately warned of the risks and complications,
19 you're basing that on just from the perspective
20 of being a medical doctor who works in this field
21 reading it and saying from your perspective
22 whether or not you think it's adequate. Fair
23 statement?

24 MS. JONES: Object to the form.

1 THE WITNESS: Yes, it's based on my
2 clinical medical opinion as a clinical -- as a
3 clinician and practicing physician.

4 BY MR. SLATER:

5 Q. And in terms of the standard you're
6 applying in giving that opinion, it's basically
7 the standard is what you think is adequate from
8 your own personal perspective, correct?

9 MS. JONES: Form.

10 THE WITNESS: Well, it's my
11 perspective for clinicians that are doing this
12 type of procedure. So, I mean, the IFU is
13 designed to provide information to us as
14 clinicians. And so the question is, is there
15 sufficient information in that IFU that us -- we,
16 as clinicians, who are, you know, focusing on
17 Prolift and have experience with dealing with
18 mesh, that the information provided in that IFU
19 is sufficient for us to be guided about how to
20 perform the procedures and risks and benefits of
21 the procedures, et cetera, yes. That's a long
22 answer, but...

23 BY MR. SLATER:

24 Q. Do you agree that the information in

1 the IFU should be supported by foundational facts
2 and data?

3 MS. JONES: Object to the form.

4 THE WITNESS: Yes, I imagine that they
5 would -- you'd want data in there, not just
6 making up things, yes.

7 BY MR. SLATER:

8 Q. -- made claims to the IFU that --

9 A. I'm sorry.

10 Q. I'm sorry. If it turned out that
11 Ethicon made claims in the IFU as to the
12 qualities or attributes of the Prolift and those
13 claims were not supported by any data, you would
14 criticize that, right?

15 MS. JONES: Object to the form.

16 THE WITNESS: I'm not sure that I
17 would criticize it. I'd probably just ignore it
18 because I would think that I'm, you know, that's
19 not something that I think is consistent with my
20 knowledge and experience in dealing with meshes,
21 so I would probably just ignore that aspect.

22 BY MR. SLATER:

23 Q. As an expert in this case, if it
24 turned out and it was shown to you that there was

1 a statement made in the IFU, for example,
2 claiming some attribute of the Prolift and it
3 turned out that claim had no supporting data, as
4 an expert you would say that's something you
5 criticize, Ethicon should not have done that,
6 right?

7 MS. JONES: Same objection.

8 THE WITNESS: I mean, I don't think --
9 I don't think that Ethicon's statement regarding
10 that one way or the other would influence my
11 decision-making as a clinician. So, yeah, in the
12 perfect world --

13 BY MR. SLATER:

14 Q. That's not my question.

15 A. In the perfect world, yeah, they
16 probably shouldn't have put that into the IFU,
17 but I don't think that their statement in the IFU
18 to that effect would influence me one way or the
19 other regarding my understanding of the product
20 and my use of it as a clinician.

21 Q. I haven't even given you content.
22 This is a question in general, so I'm not sure
23 why you're saying it wouldn't impact your
24 decision-making when I haven't even asked you

1 content-wise what it would be. So let's go back.

2 MS. JONES: Move to strike comments of
3 counsel.

4 BY MR. SLATER:

5 Q. I'm asking you a straightforward,
6 general question. If it turned out that Ethicon
7 made claims about the Prolift in the IFU that
8 Ethicon did not have support for, did not have
9 data to support it, you would criticize that,
10 correct?

11 MS. JONES: Object to form.

12 THE WITNESS: I have answered that
13 already.

14 BY MR. SLATER:

15 Q. Would you agree with me that that
16 would be a violation of Ethicon's duties or do
17 you not know?

18 A. I mean, it's not -- the -- Ethicon's
19 duty of what it is required to do or not do is
20 something that is difficult for me to say from a
21 legal standpoint.

22 From a clinician's standpoint, I feel that
23 the -- what is placed in the IFU, since the IFU
24 is designed to be information to the provider but

1 not a substitute for medical care and textbooks
2 and information of what you know, I am going to
3 take most of what's in that IFU with a grain of
4 salt regardless.

5 Q. Do you think the IFU is an important
6 document?

7 A. I think it's a document that's, you
8 know, that is required to be written, but it's a
9 document that each physician who's going to
10 potentially be treating Prolift -- or treating
11 prolapse and doing a Prolift, they have to
12 evaluate based on the context of their medical
13 knowledge whether they agree with the statements
14 that are in the IFU or not. I mean, the IFU is
15 not the end all -- I'm sorry. The IFU is not the
16 end-all be-all for information for physicians
17 regarding this particular procedure.

18 Q. Do you know from a regulatory
19 perspective what the purpose of the IFU is, the
20 specific purpose?

21 A. From a regulatory standpoint, no.

22 Q. You don't know from the perspective of
23 Ethicon Medical Affairs as to what purpose they
24 thought the IFU had, correct?

1 A. I don't know what they thought, no.

2 Q. When you evaluate whether or not the
3 warnings in the IFU are adequate or not and
4 whether the information is adequately provided or
5 not, the standard you're applying is you, as
6 Dr. Horbach, based on your experience, what you
7 think is appropriate or not, correct?

8 MS. JONES: Object to the form, asked
9 and answered.

10 THE WITNESS: I'm stating that it's
11 based on my opinion as a practicing
12 urogynecologist who has experience dealing with
13 prolapse surgery and with meshes as is part and
14 parcel of what this product was indicated for and
15 specifically what it states in the IFU. I think
16 I'm basing my opinion based on that, not just my
17 personal opinion, but what those of us in the
18 community who do this type of work and who do
19 treatment with mesh, what our understanding would
20 be regarding the procedure and the potential
21 positives and negatives about the procedure.

22 BY MR. SLATER:

23 Q. Are you applying any specific
24 objective standard to whether or not the IFU

1 warnings are adequate?

2 A. Not a specific objective standard.

3 It's a clinical standard, yes. It's more of a

4 clinical standard, yes.

5 Q. It's just --

6 A. I'm sorry.

7 Q. -- that's what I'm getting at. The

8 standard you're applying to whether or not the

9 warnings and the information provided in the IFU

10 or the patient brochure or any of the other

11 documents you looked at, your standard for

12 whether it's adequate is, based on your

13 experience, what you think is adequate and

14 reasonable; is that fair?

15 MS. JONES: Form.

16 THE WITNESS: Yes, it's based on

17 clinical experience and clinical judgment and

18 expertise, yes.

19 BY MR. SLATER:

20 Q. You're not applying any specific

21 standard whether something that Ethicon was

22 holding itself up to or otherwise, no objective

23 standard, correct?

24 A. Correct.

1 Q. Would you agree with me that Ethicon
2 should not have provided false information in the
3 IFU, the patient brochure, the professional
4 education or any of their other documents that
5 doctors and patients were going to read?

6 MS. JONES: Object to form.

7 THE WITNESS: Yes, I would agree with
8 that.

9 BY MR. SLATER:

10 Q. If it turned out that Ethicon provided
11 false information, you would criticize that,
12 correct?

13 MS. JONES: Form.

14 THE WITNESS: I would criticize it in
15 terms of what?

16 BY MR. SLATER:

17 Q. Would you say that's a violation of
18 Ethicon's duties?

19 A. Duties as what? I mean, that's a
20 legal definition.

21 Sorry. You've gone away.

22 Q. Let me ask you this question. Let me
23 ask this question. We might be able to
24 short-circuit a line of questions.

1 Is it fair to say that you are not in a
2 position to tell me what the duties of Ethicon as
3 a medical device manufacturer were with regard to
4 providing warnings and information to doctors and
5 patients? In terms of what standards or duties
6 Ethicon was required to meet, you don't have that
7 information, correct?

8 MS. JONES: Object to the form.

9 THE WITNESS: From a -- from a legal
10 standpoint, I don't have that information. I'm
11 doing this based on clinical judgment as a
12 clinician.

13 MS. JONES: Counsel, the tape, you've
14 got five minutes.

15 MR. SLATER: Okay. Five minutes
16 total?

17 MS. JONES: Yes.

18 VIDEO SPECIALIST: Four now.

19 MS. JONES: Four and a half now.

20 BY MR. SLATER:

21 Q. Do you know whether or not the French
22 TVM study met its primary endpoint?

23 A. It did not.

24 Q. It failed its primary endpoint,

1 correct?

2 A. Correct.

3 Q. That is significant, correct?

4 MS. JONES: Object to the form.

5 THE WITNESS: Significant --

6 significant in terms of what?

7 BY MR. SLATER:

8 Q. Is it significant to you that the
9 French TVM study failed its primary endpoint? A
10 simple yes-or-no question.

11 A. No.

12 Q. Did you ever look at the data for the
13 Prolift+M clinical study?

14 A. I think I do -- I think I did. I
15 don't -- trying to remember specifically. I
16 believe I did, yes, but I can't recall that.

17 Q. Can you tell me anything -- can you
18 tell me how much -- rephrase.

19 Do you know what stage the clinical study
20 for the Prolift+M was at when the Prolift+M was
21 launched?

22 A. My recollection is that it was greater
23 than stage 2 rather than greater and equal to
24 stage 2.

1 Q. Here's my question. Do you know how
2 many -- how much -- how long the Prolift+M study
3 had been ongoing at the time the Prolift+M was
4 put on the market?

5 A. Sorry. I misinterpreted your
6 question. I think it had been approximately -- I
7 think they had the six-month data compiled. The
8 one-year data was around the time period that
9 they put it on the market.

10 Q. Do you feel that was an adequate
11 amount of data to launch the Prolift+M?

12 A. Certainly within the standard of what
13 our procedures have typically -- what our
14 literature has -- it's certainly within the
15 standards of what our literature has been in the
16 past in terms of describing surgeries or new
17 surgeries and publishing literature in that
18 degree to support those procedures.

19 Q. If Ethicon only had three months or
20 less of clinical data on the Prolift+M, would you
21 agree they should not have launched the Prolift+M
22 at that point and should have waited to have data
23 for a longer period of time?

24 A. I think that would be optimal per se.

1 I'm not sure that it's below the standard of care
2 to do that.

3 I think he's trying to tell you that the
4 tape is done.

5 MR. SLATER: All right. We can change
6 the tape.

7 VIDEO SPECIALIST: The time now is
8 3:15. We are going off the record. This is the
9 end of disc number 2.

10 (Proceedings recessed.)

11 VIDEO SPECIALIST: The time now is
12 3:27. We are back on the record. This is the
13 beginning of disc number 3.

14 BY MR. SLATER:

15 Q. Do you know what the ultimate outcome
16 was of the Prolift+M clinical study?

17 A. I can't give you that information at
18 this point. No, I can't recall it.

19 Q. With regard to the actual design of
20 the Prolift, you don't hold yourself out as an
21 expert with regard to the design of the Prolift,
22 correct?

23 A. Correct.

24 Q. Same with the Prolift+M, correct?

1 A. Correct.

2 Q. I'd like to go back to one thing -- we
3 had kind of a banter off the record -- but for
4 your own benefit, did you have a chance to review
5 your list of articles to confirm that most of
6 your articles address incontinence?

7 A. Yes, that's what I had said. Yes,
8 most of my articles in the past have addressed
9 incontinence.

10 MR. SLATER: If you could, I think,
11 Sara, we have an article there, and it's
12 Dr. Horbach's article from 2009, titled De Novo
13 Stress Incontinence and Pelvic Muscle Symptoms
14 After Transvaginal Mesh Repair, could you pull
15 that out and we'll mark it as an exhibit.

16 (Exhibit No. 15 marked for
17 identification.)

18 MS. JONES: It's been marked as
19 Exhibit 15.

20 MR. SLATER: 15? Thank you.

21 BY MR. SLATER:

22 Q. Dr. Horbach, we've handed you Exhibit
23 15. For the record, this is an article titled De
24 Novo Stress Incontinence and Pelvic Muscle

1 Symptoms after Transvaginal Mesh Repair, and
2 you're one of the authors, correct?

3 A. Correct.

4 Q. And this addresses the experience of
5 your medical practice based on a retrospective
6 chart review with the Prolift, correct?

7 A. Yes.

8 Q. I just want to understand one thing,
9 going back to something you told me generally
10 before actually. You talked about a symptom
11 called levator muscle tenderness, and I believe
12 you noted that Connie Schubert has that symptom,
13 correct?

14 A. That's a sign on her examination that
15 she has, yes. It's a sign, not a symptom.

16 Q. And where would the arms of the
17 Prolift and Prolift+M be in proximity to the
18 levators?

19 A. Typically the anterior proximal arm is
20 going to be somewhat near the levators. The
21 posterior arm is typically below the levators.

22 Q. The anterior arm of the Prolift or
23 Prolift+M due to either tension or contraction
24 can cause levator muscle tenderness, spasm, pain,

1 correct?

2 A. Yes.

3 Q. Let's look at your article. Your
4 article was published in 2009, correct?

5 A. Yes.

6 Q. In the second column on the first page
7 at the very bottom you note that there is debate
8 and controversy over the appropriateness of this
9 new therapy and how it should be applied to
10 clinical practice, and you're talking about the
11 Prolift, correct?

12 A. That's it, yes.

13 Q. Just above that you say:

14 There is increasing industry
15 pressure for surgeons to adopt
16 mesh-augmented repairs into their
17 practice and many surgeons are
18 using the therapy liberally.

19 Do you see that?

20 A. Yes, I see it.

21 Q. And you were pointing that out
22 because, from your perspective, that was a
23 problem, correct?

24 MS. JONES: Object to the form.

1 THE WITNESS: That was a statement
2 that was part of our fellow's original
3 manuscript. Not all of us agreed with the
4 statement, but it is something that we left in
5 the article.

6 BY MR. SLATER:

7 Q. Well, you would agree with that
8 statement and you would agree that that's a bad
9 thing, that the industry, companies like Ethicon,
10 were pressuring surgeons to adopt mesh-augmented
11 repairs into their practice, correct?

12 MS. JONES: Object to form.

13 THE WITNESS: You know, again, I mean,
14 I personally did not have that experience and I
15 don't know that, you know -- certainly among our
16 practice we didn't have that experience. Whether
17 that was going on elsewhere, that I can't state.

18 BY MR. SLATER:

19 Q. If companies like Ethicon were
20 bringing pressure on surgeons to adopt
21 mesh-augmented repairs like the Prolift, that
22 would be a bad thing, right?

23 MS. JONES: Object to the form.

24 THE WITNESS: I think it would be a

1 bad thing only if the surgeons responded to the
2 pressure. I mean, whether -- the company --
3 sorry. The company can pressure you or whether
4 it's this company or a drug company or anybody
5 else can sit there and say, you should do this,
6 do this, but I'm not going to do anything nor
7 would, hopefully, any reasonable and competent
8 and ethical physician do something that they
9 don't believe to be appropriate regardless of
10 what they are told by company representatives or
11 pressured in any way.

12 BY MR. SLATER:

13 Q. If a company -- well, rephrase.

14 If Ethicon provided false and/or
15 misleading information to doctors in an effort to
16 get them to adopt the Prolift, that would be a
17 bad thing, right?

18 MS. JONES: Object to the form.

19 THE WITNESS: Yeah.

20 BY MR. SLATER:

21 Q. That would be reprehensible, correct?

22 A. I'm not sure that I would use that
23 word.

24 Q. Well, what word would you use to

1 describe that?

2 A. I think it would be -- it would be
3 something that -- that I would be disappointed to
4 see that the company was doing.

5 Q. If in fact it turns out in this case
6 that Ethicon provided false and misleading
7 information to Dr. Roberts, and, as a result of
8 that false and misleading information,
9 Dr. Roberts recommended and placed the Prolift
10 and Prolift+M into Connie Schubert leading to
11 these complications she has suffered from, if
12 that went on, you would agree with me Ethicon
13 should be punished for that, correct?

14 MS. JONES: Object to the form.

15 THE WITNESS: No.

16 BY MR. SLATER:

17 Q. You think it's acceptable if Ethicon
18 provided false and misleading information to
19 Dr. Roberts which Dr. Roberts believed and then
20 relied on that information in recommending the
21 Prolift and Prolift+M to Connie Schubert and
22 putting those devices in her body?

23 MS. JONES: Object to the form.

24 THE WITNESS: No, I don't think it's

1 an issue.

2 BY MR. SLATER:

3 Q. I'm talking -- let me explain
4 something before you answer. I'm talking about
5 Ethicon's conduct here. That's what I'm asking
6 you to comment on.

7 A. If Ethicon provided, you know, false
8 information to a physician, I think that that is
9 not a correct, you know -- I think that's a
10 problem that the company did, but if that -- if
11 that physician then goes on and does a procedure
12 without having, you know, any kind of
13 intellectual questioning or any kind of
14 evaluation based on their background and
15 understanding of things, then, I mean, that's the
16 physician's responsibility to question that.

17 I mean, you don't -- I mean, I don't know
18 about you, but I don't believe everything that's
19 advertised to me. I don't believe everything I
20 see on TV or hear on TV. I don't make my
21 decisions based on that nor do most people.

22 So, as a clinician, it is our
23 responsibility to weigh what we are told or
24 information that we get from multiple sources,

1 whether it's a company, whether it is a article,
2 whether it's a national organization, and weigh
3 the accuracy or not of that -- of that
4 information in making a decision about how we
5 manage patients.

6 BY MR. SLATER:

7 Q. Do you know if Ethicon expected
8 doctors to believe what Ethicon was telling
9 doctors about the risks and benefits of the
10 Prolift?

11 A. I can't say what Ethicon believed or
12 not believed.

13 Q. Okay. That was my question. If in
14 fact Ethicon provided false and misleading
15 information to Dr. Roberts in the professional
16 education that he actually attended that was
17 sponsored by Ethicon, and, as a result of that
18 information, Dr. Roberts put the Prolift and
19 Prolift+M into Connie Schubert's body, Ethicon
20 should be punished for providing that false and
21 misleading information in professional education
22 that it was sponsoring and providing, correct?

23 MS. JONES: Object to the form. It
24 calls for legal conclusion.

1 THE WITNESS: I don't -- I mean, I
2 don't agree with that. I think --

3 BY MR. SLATER:

4 Q. That's all I asked you. You don't
5 agree. I'm not asking for your explanation.

6 A. Okay. No.

7 Q. If Ethicon provided false and
8 misleading information in the patient brochure
9 for the Prolift and if Dr. Roberts relied on that
10 information in speaking with Connie Schubert and
11 in recommending the Prolift to Connie Schubert,
12 should Ethicon be punished for providing that
13 false and misleading information in the patient
14 brochure?

15 MS. JONES: Object to the form.

16 THE WITNESS: I mean, I can't make
17 that statement one way or the other. I mean,
18 it's not my role to decide whether Ethicon should
19 be punished or not for something.

20 BY MR. SLATER:

21 Q. Would you agree with me that Ethicon
22 needed to tell the truth when it provided
23 information to doctors and patients?

24 MS. JONES: Object to the form.

1 THE WITNESS: I would expect that they
2 were telling the truth when they provided the
3 information.

4 BY MR. SLATER:

5 Q. If Ethicon knowingly provided false
6 information to doctors and/or patients, you would
7 agree with me that would be wrongful, right?

8 MS. JONES: Object.

9 THE WITNESS: Again, that's a more of
10 a legal conclusion, I think, than it is from a
11 clinical standpoint. So that I think I would
12 have a hard time giving you an answer one way or
13 the other.

14 BY MR. SLATER:

15 Q. Let's look at your article, your 2009
16 article, and let's go to the second page,
17 right-hand column, 73.e2, right-hand column, just
18 towards the top, about eight lines down, it says:

19 For our study we defined pelvic
20 muscle symptoms as pelvic-floor
21 symptoms attributed to pelvic
22 muscle dysfunction that persisted
23 greater than 12 weeks beyond
24 surgery.

1 That was your definitional terminology for
2 this study, correct?

3 A. Yes.

4 Q. And you explain:

5 We restricted these symptoms,
6 meaning those that fit into that
7 category, to the sexual function
8 and pain subcategories of the
9 International Continence Society's
10 definition of pelvic muscle
11 dysfunction, which specifically
12 included new onset or worsening
13 dyspareunia and vaginal pain.

14 Correct?

15 A. Correct.

16 Q. And then you say, you also included
17 within that definition, findings and symptoms
18 that were attributed to the pelvic floor that are
19 specific to vaginal mesh procedures including
20 groin pain, buttock pain, pain with sitting and
21 pain with walking.

22 Do you see that?

23 A. I see the statement, yes.

24 Q. So you would agree with me that

1 symptoms that are specific to vaginal mesh
2 procedures include groin pain, buttock pain, pain
3 with sitting and pain with walking, correct?

4 A. I don't think they are specific for
5 just vaginal mesh procedures. I think that they
6 are specific for vaginal procedures or even some
7 abdominal procedures.

8 Q. Why did you use that terminology,
9 then?

10 A. That was terminology that was written
11 by the primary author. Again, we go through a
12 dialogue regarding what ends up being in the
13 final version of the article but doesn't
14 necessarily mean that all of us view that as the
15 only thing. And I think it's -- the implication
16 is different than what it was intended to be.

17 Q. Did you review this article before it
18 was published?

19 A. Yes, I did.

20 Q. Did you ask to have that language
21 changed?

22 A. I don't recall.

23 Q. When you performed Prolift procedures,
24 did you attempt to perform the procedure in a

1 tension-free manner?

2 A. Yes.

3 Q. And what is your definition of
4 tension-free in the context of the Prolift?

5 A. It is placing -- there's two aspects
6 of it. There is one aspect of the mesh patch
7 itself and there is another aspect relative to
8 the arms of the Prolift.

9 So that in the arms of the Prolift, when
10 you are adjusting the length of those arms, there
11 is a surgical methodology to try to keep the arms
12 as loose as possible or to not have any traction
13 applied to the arms.

14 So once the arms are withdrawn through the
15 cannula, simply just to put that physically in
16 the space, then you return the anatomy to its
17 proper position and you actually push back on the
18 arms to try to -- trying to think of the right
19 word -- to try to bring the arms back through the
20 tissue.

21 So you've pulled it forward, but you try
22 to back up the arms essentially by applying
23 pressure to the area where the arms join the
24 patch and try to ensure, then, that, once you

1 remove the cannula, that that is -- that arm
2 placement does not involve any type of
3 palpable -- you know, that you're not feeling any
4 linear type of palpable object, I guess, is the
5 best word here in that area. So that if you were
6 then to palpate the tissue or palpate the mesh
7 area without the cannulas being in place, you do
8 not feel essentially that the mesh is there.

9 Q. And what -- you said there's two parts
10 to tension free. One part is that, when the arms
11 have been placed, you adjust the length, you keep
12 the arms as loose as possible, and so that when
13 you palpate it there -- it would not feel like
14 the arms are there, right?

15 A. Correct. And then the second part is
16 relative to the patch, that the patch is simply
17 laid under the vaginal wall between either the
18 vaginal wall and the bladder or the vaginal wall
19 and the rectum, that you do not sort of -- you do
20 not pull it taut side to side or superiorly to
21 inferiorly. Typically you do not -- you
22 certainly don't usually attach sutures to the
23 lateral margins. You may use a suture to tack
24 the mesh inferiorly or superiorly, but typically

1 that is not with anything that's permanent.
2 That's an absorbable type of suture. And you
3 avoid trying to overtrim the material itself and
4 avoid any type of trimming of the vaginal wall so
5 that you leave, purposely leave, redundancy
6 within the vaginal wall to allow for appropriate
7 healing of the combination of the mesh and the
8 vaginal wall.

9 Q. In the patients that are described in
10 this article, you and the others in your practice
11 performed what you've defined here for me as a
12 tension-free placement of a Prolift, correct?

13 A. That's what we attempted to perform,
14 yes.

15 Q. And even despite you being four
16 fellowship-trained surgeons that you would
17 consider to be highly skilled, including
18 yourself, you still ended up with contraction of
19 mesh in patients that you attribute to tension,
20 correct?

21 A. I think that that was more in the
22 earlier stages of our work with prolapse --
23 Prolift. I think that we over a period of time
24 developed some adjustments that allowed us to

1 have less of that occur, at least that was my
2 personal experience. I did not go back and
3 review --

4 Q. Move to -- I'm striking your answer
5 because it wasn't, from my perspective,
6 responsive. My question is very simple.

7 Despite yourself and the other
8 fellowship-trained surgeons in your practice
9 attempting to obtain a tension-free placement of
10 the Prolift, as you just defined it for me a
11 moment ago, you still had patients who had
12 contraction of the mesh that you attributed to
13 tension either from leaving excessive tension on
14 the mesh or due to the fact that the contraction
15 of the mesh caused tension itself, correct?

16 A. Yes, there were patients in this
17 series where that was the case.

18 I'm sorry. You're lost.

19 Q. I'm sorry. So even a doctor who is
20 highly skilled, who is following the training per
21 Ethicon, as you understood it, trying to place
22 the mesh in a tension-free way, you can still end
23 up with tension and contraction leading to
24 painful symptoms, correct?

1 MS. JONES: Object to the form.

2 THE WITNESS: Yes. Even if you place
3 it correctly, yes, you can.

4 BY MR. SLATER:

5 Q. Now, what you call pelvic muscle
6 symptoms, you're not ruling out the potential
7 that there is nerve involvement leading to this
8 pain as well, correct?

9 A. Yes, usually you -- in our use of the
10 term, we usually have tried to eliminate that
11 that was specifically related to nerve injuries.

12 Q. Do you know whether or not Ethicon
13 Medical Affairs had the understanding that where
14 a patient had contraction accompanied by pain
15 that that likely was due to nerve entrapment and
16 nerve involvement? Do you know whether Medical
17 Affairs held that view?

18 A. I don't know.

19 Q. Some of the patients in your study, in
20 fact 35% of them, were only stage 2 prolapse when
21 you operated on them, meaning you and your group,
22 correct?

23 A. I believe that's what the information
24 states.

1 Q. Were you ever aware that Ethicon
2 intended the Prolift to be used in stage 3 or 4
3 prolapse?

4 MS. JONES: Object to the form.

5 THE WITNESS: I believe I saw
6 something to that effect, although the --
7 ultimately it was designed or marketed for stage
8 2 or greater.

9 BY MR. SLATER:

10 Q. The prolapse -- rephrase.

11 The Prolift was marketed for pretty much
12 anybody that a doctor wanted to put it into as
13 long as the patient wasn't a child or wasn't
14 going to be getting pregnant; other than that,
15 there were no limitations in the materials that
16 marketed the Prolift, correct?

17 MS. JONES: Object to the form.

18 THE WITNESS: I don't think that
19 that's necessarily true. I mean, there were
20 other patients that they felt or that the patient
21 education information, et cetera recommend that
22 those were -- the Prolift was potentially
23 counter-indicated in those patients.

24 BY MR. SLATER:

1 Q. When did they start putting that
2 information in the professional education, what
3 year?

4 A. I'd have to go back and look at the
5 specific slides to let you know, but -- I don't
6 recall whether it was -- exactly when it was. It
7 was probably in the --

8 Q. It certainly --

9 THE REPORTER: I'm sorry. Excuse me.
10 Counsel, wait. I did not hear the remainder of
11 the doctor's answer.

12 "It was probably in the..."

13 THE WITNESS: It may or may not have
14 been in the first set, but I think it was in the
15 second set of professional education materials.

16 BY MR. SLATER:

17 Q. You would agree with me that Ethicon
18 at least internally intended the Prolift to be
19 used for stage 3 and 4 prolapse, correct?

20 A. I don't know whether that's the case.

21 Q. You would agree with me that, based on
22 your experience over the course of years, you
23 reached the conclusion that the Prolift really
24 should be limited to stage 3 and 4 prolapse,

1 correct?

2 A. I did not reach that conclusion.

3 Q. In reporting your results you
4 understood that somebody with a stage 2 prolapse
5 would have a much less like -- much lower
6 likelihood of a recurrence than someone at stage
7 3 or 4, correct, in general terms?

8 A. In the general data regarding Prolift
9 recurrence, yes.

10 Q. You note on page e3, in the right-hand
11 column, that of the 290 women who completed
12 greater than or equal to 12 weeks of follow-up,
13 18.3% experienced pelvic muscle symptoms
14 postoperatively including new onset dyspareunia,
15 vaginal pain, groin pain, pain with walking and
16 pain with sitting, correct?

17 A. That's what it states.

18 Q. So that is 18.3% of the patients
19 having at least three months of pain following
20 Prolift surgery, correct?

21 A. That's what it states.

22 Q. And in 25% of those women the pain did
23 not resolve within six months and continued
24 beyond six months, correct?

1 A. I think that that was the information.
2 I'd have to double-check.

3 Q. It's right there. It says, in 74% of
4 these women --

5 A. Okay. Sorry.

6 Q. -- the symptoms resolved within -- I'm
7 sorry. So am I correct?

8 A. Yes. I did it the opposite -- you
9 changed the numbers around, so --

10 Q. And it indicates that in 14 patients
11 we were not able to document resolution of their
12 pelvic muscle symptoms within six months. The
13 outcome of these 14 cases is listed in Table 3.
14 Those are the 25% of the pain patients for which
15 the pain did not resolve within six months,
16 correct?

17 A. Yes.

18 Q. And you would agree with me that the
19 complications described for those 14 patients are
20 significant complications, correct?

21 MS. JONES: Object to the form.

22 THE WITNESS: I mean, the term -- they
23 are complications. Whether they are significant
24 or not, you know, that's a subjective

1 determination. From the standpoint of the
2 patients, they are probably significant issues,
3 yes. They are not the same as --

4 BY MR. SLATER:

5 Q. -- patients described in this table
6 are clinically significant, correct?

7 A. They are having clinical symptoms,
8 yes.

9 Q. Turn to page e5, if you could. In the
10 middle column you talk about in your current
11 study 3% of the women experienced continued
12 pelvic-floor-related discomfort after the Prolift
13 procedure that does not respond to conservative
14 therapy. Do you see that?

15 A. Yes.

16 Q. So these women that are listed on this
17 table, you attempted conservative therapy with
18 them, but it did not resolve their pain, correct?

19 MS. JONES: Object to the form.

20 THE WITNESS: Yes, in the series.

21 BY MR. SLATER:

22 Q. -- indicate some cases of pelvic
23 muscle discomfort are caused by mesh bunching and
24 banding. I want to stop there. When you talk

1 about mesh bunching and banding, we're talking
2 basically about contraction of the mesh, correct?

3 A. I'm not sure you can say it's
4 contraction of the mesh versus a rolling of the
5 mesh versus an overlap the mesh. I mean, it's
6 simply --

7 Q. Do you have an understanding -- I
8 didn't mean to -- I apologize. When you pause,
9 there is a delay and then I thought you were
10 done. Go ahead.

11 A. It simply means that you're able to
12 feel under the epithelium that the -- that there
13 is more mesh material there than perhaps in the
14 adjacent area where the mesh is laying completely
15 flat and smooth, but you can't necessarily say
16 whether it's due to vertical, horizontal
17 contraction, a foldover, you know. I mean,
18 there's multiple different ways of determining
19 that. That would be independent --

20 Q. Are you aware of whether -- are you
21 aware of whether Ethicon Medical Affairs believe
22 that where you have mesh bunching, that that's
23 essentially synonymous with contraction?

24 MS. JONES: Object to the form.

1 THE WITNESS: I'm not aware that they
2 made that equivalency.

3 BY MR. SLATER:

4 Q. Are you aware of whether or not
5 Medical Affairs at Ethicon believed that, where
6 you have mesh that's either folded on itself or
7 bunched together or wrinkled, that that increases
8 the risk of developing contraction?

9 MS. JONES: Object to the form.

10 THE WITNESS: I don't know whether
11 they were aware of that information or not.

12 BY MR. SLATER:

13 Q. You would agree -- I'll ask a new,
14 clean question.

15 You would agree that where there is
16 bunching of mesh or folding of mesh or wrinkling
17 of mesh, that increases the risk of contraction
18 of the mesh.

19 MS. JONES: Form.

20 THE WITNESS: I certainly think that
21 that's a possibility. I probably would be in
22 that area more concerned maybe about erosion of
23 the mesh rather than contracture of the mesh in
24 that area.

1 BY MR. SLATER:

2 Q. Certainly you would agree that, if
3 there is bunching or folding or wrinkling of the
4 mesh, that would increase the risk for erosion,
5 correct?

6 A. That's what I just said, yes.

7 Q. In the right-hand column on this page
8 you talk about the fact that in our limited
9 experience -- rephrase.

10 You talk about in the right-hand column
11 about just above the first full paragraph, some
12 women who experience these problems seek care at
13 other institutions and women with initial pain
14 symptoms that resolve may defer follow-up as
15 well. Do you see that?

16 A. I'm just reading through it just a
17 minute. Yes.

18 Q. And you're talking about the fact
19 that, when women have complications from this
20 type of surgery, they often will go be treated by
21 somebody else for those complications, correct?

22 A. Yes. We discussed that previously.

23 Q. And you in fact cite in your article,
24 footnote 23, to an article by Blandon, Gebhart,

1 Trabuco, Occhino and Klingele from the Mayo
2 Clinic for that proposition because they describe
3 that in their article, correct?

4 A. Yes.

5 Q. In fact, in that article they pointed
6 out that where they talked about treatment of
7 women with very significant mesh complications,
8 that only 14% of those women had been referred by
9 their doctors and the rest of the women were
10 self-referred, right?

11 A. Yes, that was true in the article.

12 You disappeared again.

13 Q. Are you familiar with the Blandon
14 article?

15 A. Yes.

16 Q. And you have read that article and the
17 very significant complications and the
18 consequences of those complications described in
19 that article, correct?

20 MS. JONES: Object to the form.

21 THE WITNESS: Yes, I've read the
22 article.

23 BY MR. SLATER:

24 Q. And those complications -- and those

1 complications described in that article and the
2 consequences of those complications all apply to
3 the Prolift and Prolift+M, correct?

4 A. I don't recall whether that was the
5 only mesh kit that was discussed in the article
6 or it was more than one mesh manufacturer.

7 Q. I'll rephrase my question because I
8 wasn't clear. And I'll tell you, some of the
9 women had Prolift, some had other mesh, so that's
10 not what I was getting at.

11 The scope of complications and the
12 consequences of those complications which the
13 doctors talk about as life-altering and other
14 very severe language, those profiles apply to the
15 Prolift and Prolift+M meaning some women suffer
16 complications that severe from those devices,
17 correct?

18 MS. JONES: Object to the form.

19 THE WITNESS: Yes.

20 BY MR. SLATER:

21 Q. If Ethicon knew that on the day that
22 Prolift was launched, Ethicon would have needed
23 to warn about that to doctors and patients
24 meaning that complications that severe can occur,

1 correct?

2 A. I think that they -- that that should
3 have been included, yes.

4 Q. In this study you studied the de novo
5 stress incontinence rate and came up with 24.3%,
6 correct?

7 A. Yes.

8 Q. You did not have them do cough stress
9 tests, correct, all the women?

10 A. At what period of time? Pre or
11 post-op?

12 Q. Postoperatively -- post-op.

13 A. I don't remember whether the stress
14 incontinence symptoms were specifically
15 documented postoperatively in each of the
16 patients. I think it was primarily based on more
17 symptoms, and we would at times document it,
18 depending on if the patient was seeking --
19 depending on if the patient's symptoms were more
20 problematic and she was seeking resolution of the
21 symptoms.

22 Q. On page e2 it says, in the top right
23 column:

24 Postoperative cough stress tests

1 and urodynamics were not routinely
2 performed in women with mild
3 symptoms who did not want to pursue
4 possible surgical therapy --

5 A. Yeah, that's just what I said.

6 Q. -- correct?

7 A. That's just what I said before you
8 read it.

9 Q. So, as a result, it's likely that
10 there were some women who would have fit the
11 criteria for postoperative stress
12 incontinence who were not captured within the
13 24%, correct?

14 A. No, I think you've misinterpreted. I
15 think the 24% represent patients who presented
16 with symptoms of stress incontinence. We --
17 because we were obviously not doing a prospective
18 study, we're doing a retrospective study, not
19 every patient undergoes a postoperative stress
20 test or urodynamics to look for objective
21 evidence of stress incontinence.

22 Q. Got it. I got it. I did misread it.
23 That's what you get for reading this stuff late
24 at night.

1 On the last page of the text, page e6 in
2 the left column, the first full paragraph, second
3 sentence --

4 A. Let me get there.

5 Q. You say, visceral injury -- let me
6 know when you're there. I'll start over.

7 A. Last page. Where was it?

8 Q. -- paragraph, second sentence.

9 A. Okay.

10 Q. You say in page e6 in the left column:

11 Visceral injury, a most
12 disconcerting experience for the
13 surgeon, can be expected to occur
14 occasionally with the Prolift
15 system because of the deep level of
16 dissection and passage of the
17 Prolift guides near the bladder.

18 That's a true statement, correct?

19 A. I think visceral injury is
20 disconcerting, and I think that there is a risk
21 of it occurring at the time of a Prolift
22 procedure.

23 Q. And part of the reason is, as you
24 state there, there are deep dissections.

1 A. Yes.

2 Q. In fact, if you go further down, a
3 little further down, just below footnote 24,
4 about two-thirds of the way down, you talk about
5 the fact that the deeper level of dissection
6 required to avoid mesh exposure increases the
7 risk of injury during dissection especially a
8 cystotomy, correct?

9 A. I think that's true especially in the
10 early stages of performing Prolifts when you're
11 not as familiar or comfortable with that level of
12 dissection. I think that, once you are, as a
13 surgeon, more familiar and comfortable with that
14 level of dissection, then the risk of cystotomy
15 doesn't really end up being particularly
16 different than it is in other surgeries that we
17 do where we're in the same space such as a
18 vaginal hysterectomy.

19 Q. In the last part of this text, the
20 second column on this page, on e6, just after
21 footnote 28, you say:

22 Until prospective studies further
23 clarify the merits and deficits of
24 the Prolift vaginal mesh system, we

1 recommend that surgeons who choose
2 to incorporate it into their
3 practice include a realistic
4 discussion of potential bothersome
5 outcomes such as transient pelvic
6 muscle discomfort and de novo
7 stress incontinence into the
8 preoperative counseling, which
9 should help patients and their
10 surgeons work through these events
11 should they occur.

12 Do you see that?

13 A. Yes.

14 Q. Now, you knew at the time that the
15 pelvic muscle symptoms that you're describing
16 here that you've put under that umbrella were not
17 just transient but, for some patients, were
18 chronic or permanent, correct?

19 A. The permanent part is hard for me to
20 say. I think that certainly there can be some
21 chronicity to that, and there were some patients
22 that were more susceptible to that than others.
23 That's when we came --

24 Q. So why did you only refer to transient

1 there when you knew that these symptoms could be
2 chronic and in fact you knew from the Blandon
3 article they could be disabling?

4 MS. JONES: Object to the form.

5 THE WITNESS: Well, the Blandon
6 article doesn't describe -- is not our patient
7 population that we're talking about. We're
8 discussing it relative to the patient population
9 in this particular study.

10 So in this particular study the majority
11 of our patients did have transient symptoms. We
12 did have some patients who ended up experiencing
13 symptoms for a longer period of time, and they
14 would then have continued physical therapy or
15 they would have other treatments issues to be
16 able to try to resolve the problems. Some of
17 those patients had resolution of their problems.
18 Some of those patients were, you know, lost to
19 follow-up.

20 So it's -- it's hard for me to say that
21 the symptoms are going to be permanent and
22 disabling and life threatening in the patients
23 we're talking about in this article versus the
24 Blandon article.

1 BY MR. SLATER:

2 Q. You're not just talking about your
3 patients because just above that you're talking
4 about the recent report of superior outcomes in
5 randomized controlled trials with polypropylene
6 augmented repairs, et cetera. You're talking in
7 this article, not just about your own patients,
8 but it's your patients and your review of the
9 literature, correct?

10 MS. JONES: Object to the form.

11 THE WITNESS: Yes, to a certain
12 extent, but we're saying that, yes, the symptoms
13 are most commonly transient, that -- we didn't
14 put down and can be permanent. I can't give you
15 a reason for why that wasn't included per se.

16 BY MR. SLATER:

17 Q. You should have recommended that the
18 patients be warned, not only about transient
19 pain, but chronic pain as well, correct? That
20 would have been more reflective of what you
21 actually learned in this study, right?

22 MS. JONES: Object to the form.

23 THE WITNESS: I think it would have
24 been -- if we had stated that a small number of

1 women would have potentially chronic symptoms, I
2 think that that is correct.

3 BY MR. SLATER:

4 Q. Now, there are disclosures on the
5 front page, do you see that, about people's
6 background and where they came from?

7 A. Yes.

8 Q. Why was it not disclosed that
9 Dr. Welgoss was working as a paid consultant for
10 Ethicon, the manufacturer of the Prolift device
11 that was being described in this article?

12 A. I can't answer that.

13 Q. It should have been disclosed, right?

14 MS. JONES: Object to the form.

15 THE WITNESS: I don't know, first of
16 all, whether he was doing it at that particular
17 time, and, secondly, whether or not the
18 requirements of this particular journal required
19 it.

20 BY MR. SLATER:

21 Q. I'm going to tell you, I'm right now
22 looking at an agreement that Dr. Welgoss had that
23 was signed by himself and Paul Parisi in February
24 of 2008, a year -- more than a year before this

1 article was published, and it's an agreement
2 whereby Dr. Welgoss was working with Ethicon and
3 agreeing to work as a consultant being paid
4 money. Okay?

5 So based on that, you know well enough
6 that Dr. Welgoss' consulting relationship with
7 Ethicon, the manufacturer of the Prolift device
8 at issue in this article, should have been
9 disclosed, right?

10 MS. JONES: Object to the form.

11 THE WITNESS: He may have a contract
12 with that. Whether he was actually spending time
13 doing it and/or being paid from that, I don't
14 know. So I wasn't responsible --

15 BY MR. SLATER:

16 Q. Doctor, can you see me?

17 A. Yes.

18 Q. Do you see what I'm holding up? These
19 are Dr. Welgoss' consulting contracts with
20 Ethicon. We have them all --

21 A. That's fine.

22 Q. -- something called a Defense Fact
23 Sheet, and there are cases where he treated
24 patients that had complications. And I've got

1 years of Dr. Welgoss getting paid money by
2 Ethicon to act as a paid consultant.

3 So here's my question. Here's one going
4 back to 2006 also signed by Paul Parisi. I mean,
5 I could go through this with you chapter and
6 verse, but here's my question. So here's my
7 question.

8 In light of the fact that Dr. Welgoss
9 worked for years as a paid consultant for
10 Ethicon, including for several years before this
11 article was published, you would agree with me
12 that the right thing to do would have been to
13 disclose Dr. Welgoss' consulting relationship
14 with Ethicon in this article, correct?

15 MS. JONES: Object to the form and
16 move to strike the testimony of counsel.

17 THE WITNESS: Okay. I think that, if
18 that is indeed the case, which I was not aware of
19 or not, then -- and the requirements of the
20 journal require you to disclose that, then it
21 should have been disclosed. I disclose whether
22 or not I have a -- or I have a relationship. I'm
23 not responsible for disclosing whether or not one
24 of the other authors appropriately discloses

1 their relationship that I wasn't even aware of.

2 BY MR. SLATER:

3 Q. Well, you didn't know that Dr. Welgoss
4 was working as a paid consultant with Ethicon,
5 your own partner?

6 A. We had that discussion previously,
7 and, no, I did not know that.

8 Q. You're familiar with the conflict of
9 interest disclosure requirements for the American
10 Journal of Obstetrics and Gynecology. You know
11 what those were. You're familiar with that.

12 A. I would have to go back and read the
13 specifics, but, again, that is something that is
14 not part of what I was aware of or not, and
15 whether you think it's unusual or not, I had no
16 awareness of his relationship. We function
17 fairly independently of each other, and what he
18 does separately I'm not always aware of.

19 Q. Dr. Welgoss had input into the writing
20 of that article, right?

21 A. He would have reviewed it from the
22 standpoint of, you know, saying yes or no he
23 agrees with this or not. I don't know whether or
24 not he specifically made any changes in the

1 article. The primary people writing the article
2 were going to be Dr. Aungst, who was our fellow
3 at the time, and that was reviewed primarily by
4 Dr. Von Pechmann, who was the primary person
5 working with him to edit this.

6 Q. Dr. Welgoss had input into the
7 language that was used in that article, correct?

8 MS. JONES: Objection, asked and
9 answered.

10 THE WITNESS: I can't tell you that he
11 did or didn't. I don't know whether he wrote --
12 read the article or didn't read the article or
13 whether or not he changed anything in it or
14 didn't change anything in it. You'd have to ask
15 him.

16 MR. SLATER: Sara, do you have the
17 website information?

18 MS. GARDNER: Yes, there was one
19 marked as Exhibit 8.

20 MR. SLATER: Is it the one that says
21 Mid-Atlantic Urogynecology and Pelvic Surgery and
22 then it says Surgical Mesh on it?

23 MS. GARDNER: Yes.

24 MR. SLATER: Let's use that exhibit as

1 the next one. It's Exhibit 8?

2 MS. GARDNER: Yes.

3 (Exhibit No. 8 marked for identification.)

4 BY MR. SLATER:

5 Q. Doctor, what we've provided you is a
6 page from the website for your medical practice
7 that was printed yesterday. Do you recognize
8 this?

9 A. In reality, probably not.

10 Q. Well, you would agree with me that you
11 would only put truthful information on your
12 medical practice website, right?

13 A. I would expect that that would be the
14 case, but I did not -- let me back up. Our
15 practice as of less than a month ago separated
16 from a joint practice of gynecologists and -- or
17 sorry -- urogynecologists, the four of us, as
18 well as gyn/oncologists. During that time period
19 there has been a lot of transitions and changes.

20 One of the physicians in our former group
21 was primarily responsible for drafting the
22 changes that were going to be addressed in the
23 new website. I personally had not seen that nor
24 did I have input in it at that time period given

1 other responsibilities that I had. So that's why
2 I said I have not seen it. I would expect that
3 what we would place on the website would be
4 truthful.

5 Q. What you're looking at in Exhibit 8
6 was taken from your medical practice website, it
7 was printed yesterday, and this website would be
8 intended for patients to read to get information
9 about you, the other doctors and about various
10 medical treatment that your practice offered,
11 correct?

12 A. Yes, one would expect so.

13 Q. Now let me ask you this. Did Ethicon
14 have any impact into the content on your website
15 at any point before today?

16 A. I certainly don't believe so. We have
17 not had any funding or relationship with them to
18 be able to draft this particular website, no.

19 Q. Let's look at this page that says
20 "Surgical Mesh." If you could, let's look at the
21 second paragraph. It says, in recent years the
22 FDA has received ongoing reports of complications
23 following the use in gynecologic surgery -- the
24 use of mesh in gynecologic surgery. Do you see

1 that?

2 A. Yes.

3 Q. Then it talks about the fact that the
4 FDA conducted a systematic review of the
5 scientific literature to learn more about the
6 safety and effectiveness of mesh in surgery for
7 prolapse and SUI. Do you see that?

8 A. Yes.

9 Q. Your website says, based on a thorough
10 assessment, the FDA determined that there is not
11 conclusive evidence that using transvaginally
12 placed mesh in prolapse repairs improves outcomes
13 and it may expose patients to greater risk. Do
14 you see that?

15 A. Yes.

16 Q. And that was placed on your website
17 because you thought that was important
18 information for patients to know, correct?

19 MS. JONES: Object to the form.

20 THE WITNESS: It was placed on our
21 website because of the fact that, when we see
22 patients, we oftentimes do end up recommending a
23 procedure that may involve mesh, whether it's a
24 sacrocolpopexy, whether it's a TVT, et cetera,

1 and based on the press related to mesh, and, you
2 know, litigation, if a patient hears the concept
3 of mesh or hears the word mesh, they assume that
4 that means the -- entirely the same thing and the
5 same risks exist for all procedures.

6 So in an attempt to try to stratify some
7 of the issues that we now know relative to
8 procedures involving mesh, not involving mesh,
9 you know, laparoscopic TVTs, et cetera, this is
10 an attempt for -- for us to explain that there
11 are variations in the use of mesh in different
12 procedures, and that there are different
13 complications associated with those.

14 Q. With regard to transvaginally placed
15 mesh kits like the Prolift, you referred just a
16 moment ago to issues we now know. Would you
17 agree with me that you know a great deal more now
18 about the scope of risks and complications and
19 the consequences of something like the Prolift
20 than what was known when they first went on the
21 market in 2005 --

22 A. Yes.

23 Q. -- and the years after that? Okay.

24 A. Yes.

1 Q. So, for example, the scope of risks,
2 the scope of complications, the consequences of
3 those complications, the adverse events, in other
4 words, you know more about that now than you knew
5 back when the Prolift went on the market, fair?

6 A. I think we -- we know -- the events
7 themselves and what can happen was known at the
8 time this went on the market by -- or was
9 suspected at the time this went on the market by
10 pretty much any surgeon that was involved with
11 the use of mesh. We knew that those specific
12 adverse events could occur when mesh was used,
13 whether it was done with Prolift or transvaginal
14 patches or abdominal patches, et cetera. I mean,
15 mesh in and of itself creates a certain set of
16 risk.

17 As to the frequency of those complications
18 or not occurring, I think we have a better
19 understanding of that now than what we did when
20 Prolift was initially launched. We also have a
21 better understanding of who may be more at risk
22 for those complications as well as steps that can
23 be taken to try to mitigate those complications
24 following -- or with the use of mesh and

1 regardless of which way the mesh is placed.

2 Q. Would you also agree that you know
3 more about the consequences of the adverse events
4 in terms of how severe they really can be?

5 MS. JONES: Object to the form.

6 THE WITNESS: Yeah, I think that's
7 true across the board for any mesh, whether
8 it's -- yes, for TVT -- I'm sorry -- for Prolift,
9 yes, and all mesh, basically all mesh procedures
10 we do.

11 BY MR. SLATER:

12 Q. You state on this website, the third
13 paragraph down, there is a thin little website --
14 thin little paragraph. Let me start over.

15 The third paragraph under Surgical Mesh
16 says:

17 The focus of the FDA's patient
18 safety advisory, the new
19 regulations being considered and
20 the class action lawsuits
21 undertaken involve transvaginal
22 mesh for pelvic organ prolapse
23 repair, not transabdominal mesh for
24 prolapse or mesh for SUI.

1 Do you see that?

2 A. I see that, yes.

3 Q. And is that what you were basically
4 referring to a moment ago, that you wanted to
5 make sure patients understood that the area the
6 FDA was most concerned about was the mesh kits
7 like the Prolift and the FDA was not focused on
8 mesh that was used through either abdominal
9 sacrocolpopexy or for stress urinary incontinence
10 treatment, that there was much less concern about
11 those?

12 A. That was the purpose of that
13 statement.

14 Q. Let's go down to the very bottom under
15 "transvaginal mesh." It says:

16 Transvaginally placed mesh is
17 associated with higher complication
18 rates than traditional vaginal
19 surgery or sacrocolpopexy.

20 That's a true statement, correct?

21 A. I think in the literature that's
22 probably correct, yes. In our experience I'm not
23 sure that I would agree with that, but I think in
24 the literature, yes.

1 Q. And when you report -- when you refer
2 to your experience, you're talking about you and
3 your practice group, right?

4 A. Correct.

5 Q. You then state:

6 In particular, these products are
7 associated with serious adverse
8 events including vaginal mesh
9 erosion, a complication that can
10 require multiple surgeries to
11 repair and may result in continued
12 pain even after mesh removal.

13 And that's a true statement,
14 correct?

15 A. Yes.

16 Q. And that would be a true statement for
17 the Prolift and Prolift+M, correct?

18 A. Yes.

19 Q. You then state, on this website,
20 compounding the concerns regarding adverse events
21 are performance data that fail to demonstrate
22 improved clinical benefit over traditional
23 non-mesh repair.

24 And that's a true statement, correct?

1 A. They have failed to demonstrate
2 subjective benefits. There is some data to
3 support that there may be preferential anatomic
4 outcomes for the mesh versus a traditional
5 non-mesh repair.

6 Q. That would be true for the Prolift,
7 correct?

8 A. Yes.

9 Q. And for the Prolift+M, correct?

10 A. Yes.

11 Q. When you referred to subjective versus
12 anatomic outcomes, you're talking about, for
13 example, the Altman study in 2011 where they
14 found that with anterior Prolift they could get a
15 better anatomic repair in terms of less prolapse,
16 but from a subjective functional quality of life
17 standpoint the patients reported basically the
18 same results, correct?

19 A. I think the Altman study is one of
20 them. There were, I think, other studies that
21 showed somewhat similar results. There are
22 studies that -- well, I'll stop there.

23 Q. It's come -- rephrase.

24 In your medical field the understanding

1 has evolved over the years that the focus really
2 needs to be on the functional quality of life
3 outcomes whereas the focus had originally been on
4 the anatomic outcomes. Fair statement?

5 MS. JONES: Object to the form.

6 THE WITNESS: I think that there has
7 been a pendulum. I think that the pendulum
8 currently is more in looking at the subjective
9 information as opposed to strict anatomic
10 criteria on examination, but the pendulum used to
11 be looking at subjective criteria only and then
12 it flipped to objective anatomic and now it's
13 flipped back to more of the subjective quality of
14 life. I don't know that we have a -- an
15 agreement per se of what is the optimal outcome
16 measure that we need to do in these studies.

17 Q. You would agree with me that, in terms
18 of patients and what women are looking for, they
19 are most concerned with how they feel, how they
20 function and what they are comfortable with as
21 opposed to what you might measure on an exam,
22 correct?

23 MS. JONES: Object to the form.

24 THE WITNESS: I think that that's

1 the -- yes, that that is most patients' goals
2 with surgery. And then part of what we discuss
3 is, you know, or what a surgeon should discuss
4 with a patient is what is their specific goals
5 for the surgery because patients have varying
6 goals and they can be achieved with various
7 success with different types of operations.

8 BY MR. SLATER:

9 Q. Let's look at Exhibit -- if you could,
10 Sara, if could you give Exhibit 7? It's an email
11 from September 2006.

12 THE REPORTER: Counsel, just for the
13 record, her name is Stephanie.

14 MR. SLATER: Oh, did I say Sara?

15 THE WITNESS: Are we done with the
16 other two exhibits that I can pass them back?

17 MR. SLATER: Sure.

18 (Exhibit No. 7 marked for identification.)

19 BY MR. SLATER:

20 Q. I've provided you Exhibit 7, which is
21 an email chain within Ethicon. If you could,
22 let's start on the second page.

23 MS. JONES: Mr. Slater, I got -- I
24 have an issue here, so just -- I need to make

1 sure what's supposed to be part of Exhibit 7.

2 MR. SLATER: It's a three-page email,
3 and the Bates numbers in the bottom right are 30,
4 31 and 32.

5 MS. JONES: Okay. I've got a separate
6 email here. I mean, this is the reason -- it's a
7 two-page one --

8 MR. SLATER: You can probably just
9 give it back to Stephanie because she probably
10 gave it to you by accident.

11 (Discussion regarding marking the
12 exhibit.)

13 BY MR. SLATER:

14 Q. On the second page of this email,
15 right in the middle of the page is an email from
16 someone named Christine Maroulis to several
17 people at Ethicon including Price St. Hilaire
18 regarding yourself, Dr. Nicolette Horbach. Do
19 you see that?

20 A. Yes.

21 Q. And it's dated September 8, 2006. And
22 what it deals with is apparently there was going
23 to be a presentation at something called The
24 Prolapse Repair Coalition and that you had agreed

1 to make this presentation based on the
2 recommendation apparently of Vince Lucente. Do
3 you see that?

4 A. I see that it's written here in the
5 email.

6 Q. Do you remember making that
7 presentation?

8 A. I have no recollection of that at all.
9 I don't know whether -- I have no recollection
10 that I did. I've never heard of -- or I don't
11 have any recollection of what the prolapse repair
12 coalition is.

13 Q. Let's look. You have this email where
14 this Christine Maroulis from Ethicon is asking --
15 is explaining that you had agreed to give this
16 presentation, and now let's go to the next page,
17 which is actually the first page, and someone
18 named Eric Globerman is providing information
19 back now to Christine Maroulis as to who you are.
20 Do you see that?

21 A. Yes.

22 Q. And he points out -- first of all,
23 Eric Globerman was the sales rep who you dealt
24 with at that time for Ethicon, correct?

1 A. I have no idea.

2 Q. Because on the prior page it says that
3 Eric Globerman was your representative --

4 A. I have no --

5 Q. -- assigned representative from
6 Ethicon.

7 A. I have no idea. I rarely if ever know
8 the names of the reps who are supposedly assigned
9 to my hospital.

10 Q. Okay. Let's look at the September 11,
11 2006 email where Eric Globerman says that you are
12 a well-known urogynecologist, you are in practice
13 with two other urogynecologists, and all three of
14 you are very big Prolift users. And then he
15 points out, her and Vince Lucente know each other
16 very well, and I believe Vince was recommending
17 her for this project. Are you with me?

18 A. Yes, I see it.

19 Q. Okay. You knew Vince Lucente by that
20 point, September 2006, very well? Is that a true
21 statement?

22 A. I mean, I knew him well. I had known
23 him since, you know, he finished training and in
24 our national meetings, yes. I mean, I interacted

1 with him at our national meetings, but, other
2 than that, not.

3 Q. Vince Lucente, is he somebody who you
4 listened to and relied on in any way with regard
5 to your decisions about the use of the Prolift?

6 A. Of whether to begin using it? I don't
7 think I relied on his input into my decision to
8 do it or not.

9 Q. He trained you, right?

10 A. I went up and, yes, spent a day with
11 him to learn how to do the procedure, yes.

12 Q. So Vince Lucente trained you. And
13 when was that? When were you trained?

14 A. I think we talked about when we looked
15 back -- I think it was like December 2005.

16 Q. Do you consider Vince Lucente to be a
17 friend?

18 A. I mean, I'd probably go out to dinner
19 with him, but he's not somebody that I'm, you
20 know, call other than for a medical or
21 patient-related issue. I don't know --

22 Q. Are you aware that within the -- I
23 apologize. I keep doing that. Go ahead.

24 A. I mean, I wouldn't know the name of

1 his wife, I don't know how many kids he has. So
2 obviously I don't know him particularly well
3 from -- from a non-medical perspective.

4 Q. Are you aware of concerns within the
5 medical community about the veracity of the
6 things that Vince Lucente has published with
7 regard to his data with the Prolift or any other
8 devices?

9 MS. JONES: Object to the form.

10 THE WITNESS: Other than the comments
11 that were made by Dr. Weber in her deposition
12 questioning the clinical measurements for
13 POP-Q -- and I don't know whether those were
14 specifically from Dr. Lucente or not -- I have no
15 awareness of his -- of people questioning the
16 veracity of his data in his presentations.

17 BY MR. SLATER:

18 Q. Before this case and this litigation
19 on the Prolift, had you ever been asked to
20 determine what information would need to be in an
21 IFU for a medical device?

22 A. No. I'm sorry. You've gone away.
23 You disappeared again.

24 Q. Same question -- new question. Before

1 this case had you ever been asked by anybody to
2 evaluate what should be in a patient brochure for
3 a medical device?

4 A. Not for a medical device. Patient
5 brochures for other things, but not for a medical
6 device.

7 Q. Did you ever consult with a
8 pharmaceutical company regarding what information
9 should be in a patient brochure?

10 A. I don't think -- I think I have in the
11 past when I was periodically consulting with Eli
12 Lilly. They may have shown me information, but I
13 don't recall that I participated in the drafting
14 or of any type of patient education brochures
15 since the medication was not ultimately -- the
16 FDA application was ultimately removed or
17 retracted.

18 Q. What pharmaceutical or medical device
19 companies have you consulted for in any fashion
20 in your career? You can just list them for me.

21 A. They are actually on my CV. I have
22 worked with Eli Lilly relative to trials for, you
23 know, Cymbalta or duloxetine for mixed urinary
24 incontinence. I was involved in a trial for

1 that.

2 I have functioned in the role of -- it's
3 not really a consultant, but I function in the
4 role of a member of a educational foundation that
5 is sponsored by Berlex Laboratories that provides
6 education for early training physicians as part
7 of trying to improve their academic career and
8 choosing who would be able to attend the meetings
9 or not.

10 This is actually not my CV. That part.

11 Thank you.

12 The Miniguard was a device that was used
13 for -- as a nonsurgical device for urinary
14 incontinence, and I guess it was Advanced
15 Surgical Intervention, I guess, was the company.

16 The bladder neck prosthesis device, it's
17 listed as J&J here. At the time I did the -- was
18 involved in the clinical trial I don't believe
19 that J&J actually owned the company. I think
20 they purchased it subsequent to the time that I
21 was involved in it. It was part of a much
22 smaller device company.

23 And then obviously it says here Terodiline
24 for Forrest Laboratories.

1 I don't recall that there has been really
2 anything else. There is a possibility that I may
3 have given a ground rounds, you know, here and
4 there at a different institution where some of
5 the expenses were covered by different either
6 pharmaceutical or device or -- company, but I
7 don't recall -- nothing that I have a specific
8 contract relationship with.

9 Q. Have you ever studied the question of
10 what surgeons in general expect will be provided
11 to them by way of information in an IFU?

12 A. No.

13 Q. Do you agree that if Ethicon modified
14 the IFU at some point to add information about a
15 risk and Ethicon knew that information from the
16 very beginning when the Prolift was first
17 launched, do you agree that information should
18 have been in the IFU from day one?

19 MS. JONES: Object to the form.

20 THE WITNESS: I think it depends on
21 what the information is. If it's a new
22 complication that was not listed in the original
23 IFU and they knew about it previously, then
24 ideally it should be there in the original IFU.

1 I think if it is information that is maybe
2 defining more specifically a complication, such
3 as the pain issue, then -- I don't know that it's
4 necessarily required that the initial IFU has
5 that information, just like we change documents
6 and we change educational information to provide
7 more details or less details about things over
8 time.

9 BY MR. SLATER:

10 Q. As you sit here now, what are the most
11 important risks you believe should be listed in
12 an IFU for the Prolift?

13 A. The most important risks... recurrence
14 of the prolapse or failure of the procedure,
15 injury to adjacent organs or neurovascular
16 injuries that would, I guess, include nerves and
17 hemorrhage, that type of thing, but usually we
18 just refer to it as injury to adjacent organs
19 and, you know, neurovascular structures.

20 Erosion, scarring, pain. There may be --
21 oh, postoperative voiding, I guess dysfunction, I
22 guess, is what you would say, voiding
23 dysfunction, whether it's voiding dysfunction
24 itself or retention issues. I think that sort of

1 falls in the whole category. And then stress
2 urinary incontinence. I think those are --

3 Q. Dyspareunia?

4 A. Dyspareunia is within the pain
5 syndromes.

6 Q. Anything else?

7 A. There may be something else that I'm
8 not recalling off the top of my head. You can
9 ask me specifically, but nothing that I'm --
10 nothing that I'm thinking of right now.

11 I mean, those are typically the risks that
12 we talk with about our patients' surgery can --
13 or any of those issues can require further
14 surgery to correct, whether it's injuries,
15 mesh-related problems, recurrence of the prolapse
16 itself.

17 Q. What about the inability to safely and
18 effectively remove mesh when necessary in some
19 patients?

20 A. I think that that is part and parcel
21 of any mesh procedure, and I think a surgeon who
22 uses mesh procedures would be aware of that.
23 Whether it needs to be specific -- I mean, I --
24 whether it needs to be specifically listed in the

1 IFU, I wouldn't necessarily say that that's the
2 case.

3 Q. Well, is your -- are you saying that,
4 if a surgeon would know the risk anyway, there is
5 no reason to list it?

6 A. Yeah, I think that -- I mean, I think
7 that if you are saying that the -- the
8 individuals who are going to be using the product
9 need to be people who are experienced with using
10 the product, then I don't think that it is
11 absolutely necessary to outline all the risks
12 that those people are already going to know
13 about.

14 Q. Well, you just gave me a list of risks
15 that you personally think anybody using the
16 Prolift would know, right?

17 A. Yes, they all -- any of the -- I mean,
18 everything that I've given you, yes, anybody
19 doing prolapse surgery, especially a prolapse
20 surgery using mesh, would know that those are
21 risks for Prolift or any other surgeries that
22 involve mesh.

23 Q. So really, based on your own
24 standards, you would not need to warn about any

1 risks in the Prolift that you listed because you
2 would assume somebody would know them already.

3 A. If you're stating that, you know -- I
4 think it's a redundant piece of information that
5 you're providing in the IFU, that if you are
6 someone who's done surgery for -- with patients
7 and have been involved with the use of mesh, then
8 you're sort of, you know, you're repeating
9 yourself.

10 I mean, it's -- it's what we say in every
11 consent form that we do that, if we're going to
12 do surgery on a patient, that there could be a
13 risk of bleeding. Well, you know, 99.9% of
14 patients know that, if they are having surgery,
15 there is going to be a risk of bleeding, but yet
16 we put it into the consent forms or -- so I think
17 there is -- there is a built-in redundancy.

18 Q. Ethicon was aware of a risk or a group
19 of patients or a patient criteria -- well, let
20 me -- let me break it down.

21 If Ethicon was aware of a risk that was
22 not generally understood in the medical
23 community, you would agree Ethicon needed to warn
24 about that in the IFU, correct?

1 A. If there was a specific risk that was
2 not generally known in the medical community for
3 people who do prolapse surgery or use meshes,
4 that that risk isn't generally known by that
5 group of -- that treating population, then, yes,
6 I think it should be included in the warning.

7 Q. You would agree with me that, if
8 Ethicon internally believed there were certain
9 patients that were not optimal patients for the
10 Prolift, that Ethicon should put that information
11 in the IFU so physicians would know that?

12 A. I think that they could place it in
13 the IFU as a suggestion or recommendation, but
14 ultimately it's the physician who is going to
15 make that decision whether or not the balance of
16 factors still weigh in favor of doing the
17 Prolift.

18 Q. Certainly to the extent Ethicon
19 Medical Affairs believed there were certain
20 patients for whom caution needed to be used, for
21 example, before putting a Prolift into that
22 woman, that's something that should be in the
23 IFUs so doctors know, hey, the people within
24 Ethicon who are responsible for this device are

1 telling you they think you need to use caution
2 before you put it into this type of a woman.
3 You'd agree that that warning should be there,
4 right?

5 MS. JONES: Object to form.

6 THE WITNESS: If it was a different
7 type of caution or warning than what would be
8 generally known for a prolapse and/or mesh-type
9 surgeries, that, yes, that they should include
10 it.

11 BY MR. SLATER:

12 Q. You would agree with me that, when a
13 patient is suffering from chronic pain following
14 a Prolift, treatment has been provided, the pain
15 continues, and the patient is left with a choice
16 of either keep living with this decreased quality
17 of life and pain or to go for the potentially
18 risky surgery to try to remove mesh, that the
19 patient is in a very difficult situation at that
20 point, correct?

21 MS. JONES: Object to the form.

22 THE WITNESS: I think if those are the
23 only two options that are presented to the
24 patient, that, yes, the patient would be in a

1 difficult situation. The question is whether
2 that is indeed the case, are there other options
3 that could be used.

4 MS. JONES: Adam, counsel --

5 MR. SLATER: Do you want to stop the
6 tape for a second?

7 THE WITNESS: I'd like to take a quick
8 break.

9 VIDEO SPECIALIST: The time now is
10 4:44. We are going off the record.

11 (Proceedings recessed.)

12 VIDEO SPECIALIST: The time now is
13 4:56. We are back on the record.

14 BY MR. SLATER:

15 Q. Doctor, earlier you mentioned that you
16 had a patient who had a broken ankle and then
17 developed dyspareunia, and did I understand you
18 correctly to think the broken ankle may have
19 caused the dyspareunia?

20 A. It actually not may have, it did cause
21 the dyspareunia.

22 Q. And how did the ankle fracture cause
23 dyspareunia?

24 A. Sort of like the child's song about

1 one bone's connected to the next bone connected
2 to the next bone, but in this particular patient,
3 because she had a broken ankle and during the
4 time of her healing she was not able to walk in
5 her normal gait and pattern, as a result, she
6 created increased strain and pressure on the hip
7 and started doing compensatory gait aspects to
8 try to protect the hip.

9 Because of the problems then with the hip,
10 she changes her body mechanics relative to the
11 muscles of the pelvis to try to compensate for
12 the pain that she was having in the hips.

13 So within a approximately 6- to 12-month
14 time period from the time of the original broken
15 ankle, even though it had healed, it ultimately
16 had the body mechanic issues that she developed
17 levator muscle spasms, and so during intercourse
18 she was experiencing pain.

19 When we treated her with physical therapy
20 for her pelvic floor muscle spasms, then her
21 dyspareunia resolved. But we traced it back to
22 the orthopedic and the different body mechanic
23 issues that were going secondary to the
24 orthopedic issues.

1 I'm sorry. You've disappeared.

2 Q. -- you treated who broke her ankle,
3 then walked differently, developed levator ani
4 muscle spasms and discomfort with sexual
5 relations had no contracted or eroded mesh in her
6 pelvis, did she?

7 A. No, she did not.

8 Q. Would you agree with me that, once a
9 woman has a Prolift or Prolift+M in her body, to
10 the extent that mesh remains, there's no safe
11 time from erosion until the woman remains at
12 lifelong risk for erosion of mesh?

13 MS. JONES: Object to the form.

14 THE WITNESS: I think that that is a
15 hard statement to make in general. I think that
16 the mesh erosion, when it occurs, has typically
17 occurred within the earlier stages
18 postoperatively, and, in addition, the mesh
19 erosions are going to occur usually in the more
20 superficial areas where the mesh is placed.

21 So that the -- it would be extremely
22 unusual to think that an arm that's along the
23 lateral pelvic sidewall or the posterior arm
24 that's inferior to the levators, if that was the

1 only remaining mesh in the patient, that that
2 itself would erode through to the surface. So I
3 think it depends on where the remaining mesh is
4 and whether the patient has a lifelong risk or
5 not.

6 Q. You would agree with me that for some
7 women they develop erosion of mesh years after
8 the Prolift is put in their body, correct?

9 A. If -- that certainly has been seen in
10 the literature for some women.

11 Q. We've marked -- let's look at Exhibit
12 3, your CV.

13 (Exhibit No. 3 marked for identification.)

14 MR. SLATER: And we can use the one,
15 Christy, that you redacted. That's fine.

16 MS. JONES: Okay. I've just done a
17 handwritten note on there for Exhibit 3. Can I
18 borrow one of your exhibit -- just write 3 on
19 there and I'll stick it on there. Thank you.

20 BY MR. SLATER:

21 Q. Is Exhibit 3 your up-to-date CV?

22 A. Yes, this is up to date relative to
23 pretty much most of what I would have in it.
24 There may be some lectures that I've done or not

1 done towards the -- that I haven't added on to
2 the very end of it, but I printed this out this
3 morning.

4 Q. Directly relevant to the issues in
5 this case that's not listed on the CV?

6 A. I don't believe so.

7 Q. Let's look at Exhibit 1, which is the
8 deposition notice.

9 (Exhibit No. 1 marked for identification.)

10 BY MR. SLATER:

11 Q. Did you see that deposition notice
12 before today?

13 A. No.

14 Q. Is this the first time you're seeing
15 it?

16 A. Yes.

17 Q. Let me ask you this. Exhibit 4 we
18 went through in some detail, your quote/unquote
19 reliance list, and you, in addition to the
20 documents and materials listed on there, you also
21 went through medical literature that may not have
22 been listed on here.

23 What I want to know is are there any other
24 documents that you've reviewed or are relying on

1 that are either not listed on this reliance list
2 or that you didn't tell me about today when you
3 went through your list of medical literature?

4 A. Not that I can recall, no.

5 Q. We're now getting to the catchall part
6 of the deposition potentially.

7 A. Can you hold for just a second? I
8 just want to make sure one thing.

9 Q. Sure.

10 A. There is -- I just was trying to see
11 if it was on my CV. There is one article that
12 came out of our group that looked at
13 complications, gastrointestinal complications
14 associated with laparoscopic sacrocolpopexy, and
15 I don't think that that's on my CV or my list.

16 So I would -- I think it's been published
17 within the last two years or so, and it's by --
18 the primary author is William Warner,
19 W-A-R-N-E-R, who is one of our fellows. I don't
20 think I'm listed as an author on that
21 particularly.

22 Q. You are actually. I'm looking at it
23 right now.

24 A. Fine. I didn't remember.

1 Q. This is an article titled Effect of
2 Operative Technique on Mesh Exposure in
3 Laparoscopic Sacrocolpopexy?

4 A. No, that's a different article.
5 That's one -- the article --

6 Q. I don't know --

7 A. The article that I'm referring is not
8 that article. That's why I wanted to make it
9 specific. It's by William Warner, and it's
10 gastrointestinal complications of laparoscopic
11 sacrocolpopexies.

12 Q. Is that article listed on your CV?
13 I'm flipping through it.

14 A. I don't think it's listed on my CV
15 because it came out of my group, but I don't
16 think I was an author on it.

17 Q. Is there anything of significance in
18 that article that you'd rely on in this case?

19 A. It talks about the, you know, risks --
20 I mean, the postoperative complications and risks
21 associated with sacrocolpopexy even if it's done
22 laparoscopically.

23 Q. In fact in the article I asked you
24 about, the 2012 article, Effective Operative

1 Technique on Mesh Exposure in Laparoscopic
2 Sacrococpopexy --

3 A. Yes.

4 Q. I'm going to withdraw that question.

5 I don't need to ask you about that. I'm trying
6 to cut through everything here. Okay.

7 During the course of this deposition we've
8 talked in great detail about many of your
9 opinions. Have we covered the opinions that you
10 hold in this case?

11 MS. JONES: Well, I'm going to object
12 to the form of the question, Adam. Talked about
13 a lot of them. She told you at the beginning the
14 different areas she was going to address. So she
15 can go back over that and so forth, but I think
16 it's a little bit unfair asking her to go through
17 each and every specific opinion.

18 BY MR. SLATER:

19 Q. Well, let me tell you what I'm getting
20 at, Doctor. I'm trying not to go through this
21 for another three years, so what I'm trying to do
22 is this. We had your disclosure, and, you know,
23 I read that, but ultimately I wanted to get into
24 the nitty-gritty with you and ask you about

1 specific issues in the case, and you've told me
2 your opinions that you hold.

3 What I want to know is whether or not
4 there is any significant opinion you hold in this
5 case that we haven't talked about today. I mean,
6 I tried to cover everything and you've told me
7 some areas you're an expert in, some you're not,
8 so I've stayed away from the areas where you said
9 you're not an expert. You've told me some things
10 you didn't have an opinion on so we understood
11 that.

12 What I want to know is, is there any
13 opinion you hold in this case that you believe is
14 significant in this case that you have not --
15 that we have not talked about today?

16 A. I think any opinion that I would be
17 discussing in addition is more specifically
18 related to the patient herself. I think that the
19 opinions that I have relative to Prolift as a
20 product or the treatment of prolapse, et cetera,
21 that we've either addressed that and/or it's in
22 the original general expert report.

23 I think we've addressed the issues about
24 the patient herself that she was a candidate for

1 -- appropriate candidate for surgical treatment.
2 We discussed some of the other alternatives, that
3 Prolift was an option for her as a choice
4 surgically. I think that -- I've also -- we've
5 also discussed the fact or I've at least
6 intimated during the discussion that the
7 complications that she has experienced following
8 her Prolift were known complications regarding
9 the Prolift surgery and are also known
10 complications regarding other surgeries for
11 prolapse and/or especially associated with mesh.

12 We've discussed that I -- my opinion
13 regarding issues for the IFU and the professional
14 education issues, et cetera. We've talked about
15 the complications that she's experiencing and why
16 I felt that she has risk factors in addition to
17 the Prolift that may be associated with the
18 complications that she is experiencing. And we
19 talked a little bit about the issues associated
20 with her disability and some of the other medical
21 aspects in her history that may predispose her to
22 some of the symptoms that she is currently
23 experiencing.

24 The issue of other opinions that I might

1 raise during the procedure or during the trial,
2 I've addressed some of -- I think most of the
3 things that I would have said relative to
4 Dr. Wall's deposition and comments that he's made
5 that I may or may not agree with.

6 We haven't really addressed too much of
7 what Dr. Weber has addressed in her deposition,
8 but there are statements in her deposition that I
9 do not agree with and would give an alternative
10 opinion.

11 Q. You mentioned other aspects in Connie
12 Schubert's medical history that may be
13 contributing to her issues. Are you talking
14 about her activity level and the work that she
15 did after she had the Prolift surgery and you
16 think that may have contributed?

17 A. And her, you know, and the associated
18 medical problems that she has, the associated,
19 you know, biomechanical problems that she has,
20 all of the things that we've talked about
21 previously.

22 Q. Well, what is the associated medical
23 problems that you're talking about?

24 A. I think that -- I mean, we addressed

1 that to some extent previously relative to her
2 prior hysterectomy surgery, her oophorectomy, her
3 hypoestrogenic state. She definitely has an
4 elevated BMI that does give some factors relative
5 to recurrent prolapse issues, et cetera. I'm
6 trying to remember if there were medical factors
7 other than that.

8 Q. Let me just stop you there. What
9 you're talking about there is that, A, you've
10 explained to me why you think Connie Schubert
11 likely had a prolapse to begin with, correct?

12 A. Yes.

13 Q. And, B, you've told me that, in
14 addition to the Prolift procedure, you believe
15 that other factors may have also contributed to
16 her having a recurrence of prolapse when she
17 eventually had it?

18 A. Yes.

19 Q. You talked about associated
20 biomechanical problems. What are --

21 A. That's what we spoke about --

22 Q. -- Connie Schubert's --

23 A. I'm sorry. That's what we spoke about
24 previously relative to some of the asymmetric

1 demands on her skeleton, on her abdominal wall,
2 on her pelvic floor based on some of the
3 orthopedic issues she has, some of the changes
4 from her prior surgeries that she's had, some of
5 the changes that are noted on the disability
6 examination. I think those have factors -- or
7 those are contributing factors for her -- some of
8 her pain issues -- and pain both in terms of her
9 complaints of constant pain plus pain in terms of
10 her complaints of dyspareunia. I --

11 Q. And, again, those would -- I'm sorry.
12 And, again, those would be combined with the
13 Prolift and the Prolift+M to contribute to those
14 complaints, correct?

15 MS. JONES: Object to the form.

16 THE WITNESS: Again, they may or may
17 not be related to the Prolift or Prolift+M. I
18 mean, you know, she didn't fracture her leg
19 previously because of the Prolift+M. She didn't
20 have other things specifically because of the
21 Prolift+M. It's these combination of issues and
22 often over time these combinations of insults or
23 defects in multiple aspects of the patient's
24 skeletal structure will have a cumulative effect

1 on a patient and can contribute to them
2 experiencing pain issues whether a Prolift is
3 there or not there. That's my comments.

4 BY MR. SLATER:

5 Q. Tell me what specific asymmetric
6 demands there are on Connie Schubert's skeleton
7 that you think may have contributed to her pain
8 and her dyspareunia and the symptoms and
9 complications that she has suffered from since
10 the Prolift surgery. Tell me specifically what
11 you're talking about.

12 A. I'm talking about that -- well,
13 unfortunately, a systematic evaluation that
14 involves -- that the skeletal muscle components
15 and the pelvic-floor issues has not really been
16 combined particularly by any clinician evaluating
17 her. However, she, you know, in her most recent
18 evaluation that she had with a -- the disability
19 examination, she is walking with a left knee
20 brace, she has a history of a left leg fracture.
21 Those, in turn, can end up, especially if there
22 is asymmetry of leg length, it can cause
23 asymmetry of hip alignment. She's got
24 restricted -- I don't remember whether it was

1 flexion or extension -- but she's got some
2 restricted range of motion in her lower
3 extremities that then can have roles in terms of
4 how it impacts a patient from a biomechanical
5 standpoint.

6 She is shorter and has a little bit of a
7 tummy like many of us postmenopausal. That can
8 create issues as women. So there is a
9 combination of factors that go on. She has seen
10 a chiropractor in the past because she has had
11 back problems and neck problems and she's had a
12 motor vehicle accident. I mean, all of these
13 things can ultimately contribute and should be
14 evaluated as part of the decision about what is
15 going on currently in her pain condition.

16 Q. Before you could offer an opinion to a
17 reasonable degree of medical probability that
18 those issues are a cause of her pain and
19 dyspareunia and issues since the Prolift, the
20 evaluation of these skeletal issues and the
21 biomechanical assessment would need to be done,
22 correct?

23 A. Before saying that those are
24 absolutely the cause of her current symptoms?

1 Yes.

2 Q. And before saying it to a reasonable
3 degree of medical certainty -- that's the
4 standard --

5 A. Nope.

6 Q. -- you would need that testing, right?

7 A. I don't think so. I think within a
8 degree -- based on my clinical practice and based
9 on my experience with patients in this type of
10 situation, it is more likely than not that some
11 of her complaints are going to be related to
12 these issues that I've addressed.

13 Q. Let me just be very clear so when I
14 walk out of here I understand what's going to
15 happen. You're going to walk into a courtroom in
16 Joplin, Missouri. You're going to sit in front
17 of a jury and you're going to tell the jury that
18 Connie Schubert, who has documented mesh
19 contraction and mesh erosions, multiple
20 operations to remove this contracted and eroded
21 mesh and actually ended up with vaginal anatomic
22 distortion that a doctor in St. Louis, named
23 Lewis Wall, had to basically reapproximate her
24 vagina and try to open it up again at the apex,

1 in the setting of all those -- of the mesh and
2 all those complications and all the surgery that
3 she has had, you're going to tell the jury that
4 you think that the reason she has pain in her
5 vagina and discomfort with sexual relations is
6 due in part to the fact that she fractured her
7 leg when she was a child and went to a
8 chiropractor to get her neck adjusted several
9 times, and whatever else you threw into that
10 list? Do I -- it's a yes-or-no question -- do I
11 understand you correctly?

12 A. Yes.

13 MS. JONES: Object to the form.

14 BY MR. SLATER:

15 Q. Okay. You do agree with me that the
16 Prolift and the Prolift+M and then the contracted
17 mesh and the eroded mesh and the surgeries that
18 were performed which would cause damage to nerves
19 and to blood vessels and devascularize the
20 tissue, and all these things that went along with
21 multiple operations, you would agree with me that
22 that is a contributing factor, even if you won't
23 say the most important contributing factor, it's
24 certainly a contributing factor causing her pain,

1 her dyspareunia and the symptoms she has been
2 complaining of in her vagina and pelvis since the
3 Prolift surgery, correct?

4 MS. JONES: Object to the form.

5 THE WITNESS: I think that
6 contributing factor from the standpoint of the
7 dyspareunia because that has been a persistent
8 complaint, the other pain issues that are more
9 recently raised in the medical record, those have
10 been very, you know, there have been medical
11 records statements that she has not had those
12 pain or the pain has been better or worse, and so
13 it's hard for me to say whether those other
14 associated symptoms are specifically related to
15 the Prolift.

16 BY MR. SLATER:

17 Q. You know that when a woman has
18 complications like what Connie Schubert has and
19 undergoes these types of multiple operations, it
20 is common for the woman to have pain that will
21 wax and wane in severity, correct?

22 MS. JONES: Object to the form.

23 BY MR. SLATER:

24 Q. You know that that occurs, correct?

1 A. I think it depends a little bit. I
2 think that may be partially dependent on what the
3 underlying reason is and what the patient's level
4 of physical activity and what are the
5 exacerbating factors for the patient experiencing
6 pain. But just sitting there and, you know, or
7 doing no change in activity, et cetera, it is not
8 particularly typical that that patient -- that
9 that pain waxes and wanes.

10 Q. You would agree with me that the
11 presence of contracting mesh, eroding mesh and
12 the multiple operations that Connie Schubert has
13 gone through over the last several years
14 certainly would significantly increase her risk
15 to develop pelvic-floor myalgia and pelvic-floor
16 dysfunction as a response to the insults of these
17 multiple operations, correct?

18 MS. JONES: Object to the form.

19 THE WITNESS: I think that is --
20 certainly that situation that you're presenting
21 can increase her risk of developing those
22 problems, yes.

23 BY MR. SLATER:

24 Q. Let me do this, if it's okay with --

1 well, actually I want to come back to one thing.

2 When I was asking you about your opinions,
3 you said you had other opinions specific to
4 Connie Schubert. Have you now refined what those
5 opinions are so I understand what they are?

6 A. I think -- yeah, I think we've gone
7 through those specific aspects of her situation.

8 MR. SLATER: Okay. What I would try
9 to do, if it's okay with the other attorneys
10 here, David, I would suggest, if you want to
11 question now, I'll look through my notes while
12 you do it. I'm pretty close to being done, if
13 not being done, and then when you finish, I'll
14 see if I have any cleanup, and then we can go
15 from there. Is that okay with you guys?

16 MR. OVERBY: It's fine with me.

17 EXAMINATION

18 BY MR. OVERBY:

19 Q. Are you okay, Doctor, to keep going
20 for a little bit?

21 A. I'm fine.

22 Q. I'm not going to be very long, but I
23 want to make sure I've covered the bases I think
24 I need to.

1 First of all, let's talk just very briefly
2 about Exhibit 4 here. Did you bring all this
3 stuff with you or just part of it today?

4 A. I have all of the medical records with
5 me. I have the transcripts of the depositions
6 that I specified previously. I have all of her
7 employment records that I've received. I have a
8 significant bulk of the articles, but I'm not
9 sure every single one of them with me. I have
10 the emails that I've received. I have -- not the
11 videos. I have the professional education
12 documents, and I have the, you know, the FDA
13 statement, the SGS statements, the IFU drafts,
14 the patient brochure drafts.

15 Q. Okay. Give you a little hint. I'm
16 going to be real short to the extent I can. So
17 the answer, I think, is, no, you don't have all
18 of it, but you have most of it?

19 A. Yes. I think the only --

20 Q. Okay.

21 A. Yeah.

22 MR. OVERBY: And here's what I'm
23 interested in. Rather than go through some of
24 this right now on the employment records and

1 medical records, I'd like to look after we're
2 done at what she has just to make sure that I've
3 got the same thing, and, if she has something in
4 addition, to get a copy of it.

5 Is that okay with you, Christy?

6 MS. JONES: I have no problem with
7 that.

8 BY MR. OVERBY:

9 Q. That's what I was really focused on.
10 You'd have a hard time getting me to look at this
11 literature very long.

12 A. Yeah.

13 Q. The literature that you did refer to,
14 though, there was a point in time when you were
15 asked about things that are more significant to
16 your opinions or something like that, I think.
17 Do you remember that?

18 A. Yes, or that I might be using at trial
19 to quote statistics from articles.

20 Q. So here's my question. I want to make
21 sure that this is -- this list is one and the
22 same.

23 Those things that you reference, that
24 literature, at least as you sit here today based

1 upon what you have and what you -- the list you
2 have in front of you, are the things that you
3 would think I might actually specifically refer
4 to that in my testimony.

5 A. Those are the things that I listed
6 more as a verbal discussion, yes, because that
7 list, I said verbally, does overlap with some of
8 this, but then there also are additional things
9 that I might have pulled up last night that
10 obviously are not on this list that I might refer
11 to.

12 Q. I understand. What you're relying on,
13 though, as far as, i.e., what's been put into
14 your data bank, your brain, is a lot broader than
15 that shorter list, true?

16 A. Oh, absolutely.

17 Q. It's probably even, to some extent,
18 broader than the reference list here in that
19 you've read stuff that's, through the years, is
20 probably not on here, true?

21 A. Absolutely. Plus I just spent
22 umpteen --

23 Q. Hours?

24 A. -- hours and hours and hours and hours

1 studying my board exams and going through a huge
2 volume of review material in addition to what I
3 have read, gathered and had the knowledge of over
4 the last 27 years that I've been a
5 urogynecologist.

6 Q. Were you doing the boards for this new
7 board that's being recognized?

8 A. Yes.

9 Q. Have you heard back yet?

10 A. Nope. We don't hear back until
11 September.

12 Q. When you were being asked a little
13 while ago about your opinions and kind of how
14 we've covered your opinions, you were looking at
15 some handwritten notes, correct?

16 A. This is the Exhibit 13.

17 Q. Okay. Can I see that real quickly?
18 Is this kind of your sort of short list to
19 yourself of the issues that you intend to cover,
20 that is, contained in Exhibit 13, or is there
21 more than that?

22 A. No, typically that's going to help me
23 sort of outline and make sure that, when he asks
24 me a question about have I given all my opinions,

1 that I can look at something rather than say off
2 the top of my head. I think the older you get
3 the more crowded your brain gets and the harder
4 it is to remember everything off the top of my
5 head.

6 Q. If I, though, were to look at the
7 notes that you have here that have been marked
8 Exhibit number 13, would this serve as a pretty
9 good outline of the areas upon which you're going
10 to or expect to give your opinion testimony in
11 this case?

12 A. Yes, that plus the original expert
13 report, yes, those are the two things that I
14 would rely on.

15 Q. And that's something -- you just
16 mentioned the expert report.

17 A. It is one of these.

18 Q. It's typed up, isn't it?

19 A. Yeah, somewhere.

20 Q. I think I saw it earlier.

21 A. It's somewhere in this stack. It's a
22 relatively large --

23 Q. Is that it?

24 A. Yeah, it's a relatively large

1 document, although -- I printed that out
2 yesterday, and I think I was just looking through
3 and there were one or two things that were maybe
4 even part of the old -- my old notes where I've
5 outlined information I was going to include in
6 there but hadn't written it out longhand.

7 Q. Here's my question. If we take, then,
8 the notes you have in 13 along with the expert
9 report that I have here in front of me, which
10 I've not seen before so I'm going to mark it --

11 What are we up to, 16?

12 (Exhibit No. 16 marked for
13 identification.)

14 BY MR. OVERBY:

15 Q. I've marked that now as 16, the expert
16 report, true?

17 A. Yes.

18 Q. If we take 13 and 16, is that a fair
19 summary of the areas in which you're going to
20 give opinions in this case?

21 A. Yes, I believe so. If you would just
22 give me that one right back again, let me just
23 make sure.

24 MS. JONES: While Dr. Horbach is

1 looking at that, just for the record, counsel,
2 that general report is a report that was prepared
3 in the New Jersey litigation and had been
4 previously forwarded to Mr. Slater and all in
5 that context.

6 MR. OVERBY: Sure.

7 MS. JONES: I'm sorry we didn't give
8 it to you.

9 MR. OVERBY: No, that's fine. I
10 understand that. I was going to cover that with
11 her that this may be more generic than just to
12 this case.

13 THE WITNESS: Right. I think that
14 that would really cover the bulk of the opinions
15 unless somebody asks me something totally out of
16 the blue.

17 BY MR. OVERBY:

18 Q. And then what we were just discussing
19 while you were looking at number 13, Exhibit 16
20 is something not created specifically for this
21 case, the opinion in Joplin, Missouri, true?

22 A. That is correct. It was -- I was
23 requested to create a general opinion regarding
24 more global aspects of prolapse and the

1 involvement of Prolift.

2 Q. You have not been disclosed in this
3 case, Connie Schubert's case, as someone who is
4 going to give standard-of-care testimony
5 regarding the care and treatment of Dr. Chris
6 Roberts. Is it true that you do not intend to
7 give that opinion?

8 A. I have not been requested to do that,
9 no.

10 Q. And as you sit here today, that's not
11 part of the list of things that you anticipate
12 explaining to the jury one way or another.

13 A. Correct.

14 Q. Okay. What I get to do today, and
15 different jurisdictions vary a little bit, but I
16 get to learn from you, to the extent you can tell
17 me, all of the opinions that you intend to give
18 at trial, but what I really want to limit my
19 questions to as they pertain to my client, which
20 is Freeman, but for the acts of Chris Roberts.

21 Do you think that you have touched on the
22 opinions that you have and intend to give to the
23 jury in this case as they touch on the care and
24 treatment of Dr. Roberts or do you think there

1 are some areas that are left uncovered at this
2 point?

3 A. No, I think that it essentially has
4 been covered based on that plus the comments that
5 I've made regarding previously that she was an
6 appropriate candidate for surgery and the
7 management that she has had to date.

8 Q. Your use of mesh has changed over the
9 years; is that true?

10 A. Yep. Sorry. Yes.

11 Q. True in medicine that there are things
12 probably that physicians do today that they
13 couldn't even do, depending on the category of
14 medicine we're talking about, five, ten, 15 years
15 ago, right?

16 A. Absolutely.

17 Q. One of the things about medicine, good
18 things, I think mostly, is it's constantly
19 changing, right?

20 A. We are -- we are -- medicine is an
21 evolutionary process. Our specialty in
22 particular is going through dramatic evolutionary
23 changes because we are very young and new
24 specialty. We are just undergoing our

1 certification aspects. We are just over the last
2 ten years been able to get NIH funding to look at
3 some of the more, you know, more difficult issues
4 within our specialty, and doing -- beginning to
5 just start doing randomized trials through that
6 and biomechanical evaluations that require a more
7 extensive funding than what can be done in
8 individual situations. So we are having a really
9 exponential growth in the information that is
10 coming out in our field and potentially its
11 impact on our clinical practice.

12 Q. There is a lot -- and I'm going to
13 tell you what I think I understand -- you tell me
14 if I get it wrong -- there is a lot more emphasis
15 today than there was just three, four, five years
16 ago on, for example, pelvic-floor muscle issues
17 and how they might impact dyspareunia, for
18 example.

19 A. Yes, I think that that's true. It was
20 something that -- our collaboration with other
21 disciplines, whether it's physical therapy,
22 colorectal, biomechanical engineers, et cetera,
23 muscle physiologists, it has allowed us to learn
24 aspects of patients' problems and patient care

1 that we may not have been aware of in our
2 isolated training as simply ob/gyn physicians or
3 urogynecologists because some of these are --
4 we're a very multidisciplinary group or our part
5 of the body is very multi-disciplinary, shall we
6 say, and there's lots of organs and lots of
7 structures in that area that can affect each
8 other, and...

9 Q. And then what -- I want to make sure I
10 understand this -- because I think earlier you --
11 very early in this deposition you said that you
12 have had some patients of yours who have
13 experienced some complications with Prolift, and
14 I may have misunderstood. Is that accurate?

15 A. Yes, I have. I mean, again, it
16 depends on what you're viewing as
17 complications --

18 Q. Right.

19 A. -- because, you know --

20 Q. And here's -- I think you were then
21 asked whether or not erosion or exposure were the
22 complications, and my memory is you said no.

23 A. In my personal practice --

24 Q. Right.

1 A. -- to my recollection I have not had a
2 patient where I've had to treat them for an
3 exposure or erosion secondary to a Prolift that I
4 placed.

5 Q. Sure.

6 A. I have -- go ahead.

7 Q. Here's what --

8 A. I've been lucky.

9 Q. What have you experienced?

10 A. I think the -- one of the issues that
11 I've experienced with Prolift is a failure of the
12 Prolift to treat the prolapse in the long term.

13 Q. So prolapse returns?

14 A. Recurrence of prolapse. A second
15 issue is the onset of stress urinary
16 incontinence.

17 Q. I think that was discussed earlier in
18 your deposition. That's a known thing that can
19 in fact be -- maybe caused isn't the right
20 word -- but exposed with fixing an anterior
21 prolapse?

22 A. Yeah, we usually refer to it as a
23 masking of the incontinence, yes. And we -- the
24 issue of voiding dysfunction, I think there have

1 been some patients in my practice that were
2 experiencing more prolonged difficulty with
3 voiding or slower voiding that required than some
4 management for it. I don't -- I certainly have
5 no one that's become catheter dependent or
6 necessary for intermittent self-catheterization.

7 And then the last group of issues are the
8 patients who have experienced some type of pain
9 component afterwards, whether it's been
10 specifically related to dyspareunia only or
11 whether it's been related to, you know, not
12 dyspareunia, but some other type of pain
13 complaint.

14 Q. So you've had patients that you have
15 operated for prolapse, installed a Prolift kit
16 into them, and they have had some dyspareunia
17 and/or other pain that they were not complaining
18 about prior?

19 A. Either not complaining about prior or
20 there may have been an exacerbation of a
21 baseline -- baseline symptoms following the
22 surgery that then subsequently required
23 treatment.

24 Q. And when you discuss voiding

1 dysfunction, I think I'm following you. There
2 could be maybe a little urinary retention and/or
3 slowing of starting your stream? Those are some
4 things that you've seen?

5 A. Right. So voiding dysfunction from
6 the standpoint of, you know, hesitancy to void,
7 slower stream, sometimes a sensation of
8 incomplete evacuate -- or incomplete emptying,
9 sometimes the -- some increased urinary
10 frequency. I forgot to add urinary tract
11 infections postoperatively.

12 So I think that would be -- we don't -- I
13 mean, urinary -- overactive bladder symptoms of
14 urgency frequency and urge incontinence, we
15 occasionally see those in postoperative patients,
16 but most of the time that's more of a transient
17 phenomenon.

18 Q. And you may have been asked this and
19 answered it and I've forgotten, so forgive me if
20 it's true. Is the only kit that you've used to
21 treat prolapse in women Prolift and/or Prolift+M
22 or have there been others in the past?

23 A. No, I have not used any other kits.

24 Q. Okay. And I think you were asked, you

1 did, though, there was a time when you would use
2 Gynemesh pieces cut up and --

3 A. My primary use of Gynemesh has been
4 more with sacrocolpopexies. In fact I still use
5 it now with sacrocolpopexies if a patient still
6 has a uterus or cervix. I don't recall really
7 placing Gynemesh as patches within the vaginal
8 area. I tended to shy away from that in my
9 previous work with vaginal repairs.

10 Q. Do you think that you have discussed
11 with me the -- and/or earlier on the record --
12 here in your deposition today the opinions that
13 you hold as they relate specifically to the care
14 and treatment of Dr. Roberts to the extent that
15 you intend to express them to the jury?

16 A. Yes.

17 Q. Doctor, I appreciate your time. Thank
18 you.

19 MR. OVERBY: I told you I'd be short.

20 MR. SLATER: I just have a couple
21 follow-up questions before Christy goes.

22 I assume, Christy, you want me to get out
23 of the way first, right?

24 MS. JONES: Please.

1 MR. SLATER: Just take a look here and
2 see what I have.

3 MR. OVERBY: She meant that in the
4 kindest of ways, I can tell.

5 EXAMINATION (resumed)

6 BY MR. SLATER:

7 Q. Doctor, a couple times a few weeks ago
8 you referred to your expert report from another
9 case, in another litigation. I don't want to go
10 through that entire report with you. The
11 opinions we've discussed today during the
12 deposition, are those your opinions in this
13 litigation?

14 A. Yes, from the standpoint of opinions,
15 I would imagine. I mean, you did not say what is
16 my opinion of, you know, how I approach -- how
17 prolapse should be evaluated, how you should
18 counsel the patient regarding surgical risks or
19 doing informed consent. There were aspects of
20 that that are part of the general report that you
21 had not specifically asked me about. I don't
22 know whether I'm going to be asked to provide
23 that information at the time of trial. But
24 whatever I would be asked relative to those

1 questions are in that report.

2 Q. With regard to the Prolift and the
3 Prolift Prolift+M specifically and Connie
4 Schubert's medical condition and the causes of
5 her condition, we've covered those issues and
6 your opinions on those issues today during the
7 deposition, correct?

8 A. Yes, I think we've covered them quite
9 effectively.

10 Q. Thank you.

11 MR. SLATER: I will now hand off the
12 mic to Christy.

13 EXAMINATION

14 BY MS. JONES:

15 Q. Doctor, I have just a few follow-up
16 reports -- questions. Let me ask specifically,
17 with respect to what I believe has been marked as
18 Exhibit 16, the report that Mr. Slater and
19 Mr. Overby have just asked you about, does that
20 report set forth general opinions relating to
21 pelvic-floor repair surgery, prolapse, Prolift
22 and Prolift+M?

23 A. Yes, it does. Although I don't recall
24 if I specifically addressed Prolift+M during that

1 document per se.

2 Q. And in that report did you also
3 address the adequacy of the information contained
4 in the IFUs and the patient brochures?

5 A. Yes.

6 MR. SLATER: Objection. You can
7 answer.

8 THE WITNESS: I address in that report
9 my opinion regarding the IFU, the patient
10 brochure, the professional education, and the
11 role of Ethicon or not in the credentialing
12 aspect of physicians for this type of surgery.

13 BY MS. JONES:

14 Q. And let me just ask -- I think it's
15 probably implicit in your comments today, but I
16 don't think the question was specifically asked,
17 so let me ask this question.

18 In your opinion, Doctor, from a medical
19 standpoint, as a clinician performing surgery and
20 using the Prolift or the Prolift+M, is the
21 information in the IFUs adequate to advise
22 pelvic-floor physicians of the risks and benefits
23 associated with Prolift?

24 A. I believe it is, yes.

1 Q. And you were asked about a number of
2 complications, including complications that some
3 of your patients have experienced who had had
4 Prolift. First of all, were those complications
5 known and recognized in the medical community at
6 the time that Prolift was first marketed?

7 MR. SLATER: Objection. You can
8 answer.

9 THE WITNESS: I think the
10 postoperative complications associated with
11 Prolift and certainly the postoperative
12 complications I've encountered with my patients
13 were known or are known complications of prolapse
14 surgery itself and especially prolapse surgery
15 associated with the placement of a synthetic
16 mesh.

17 BY MS. JONES:

18 Q. And my question is really
19 specifically, were those complications known and
20 recognized by the medical community of
21 pelvic-floor surgeons at the time that Prolift
22 was first marketed?

23 A. Yes.

24 MR. SLATER: Objection. You can

1 answer.

2 BY MS. JONES:

3 Q. And to your knowledge -- you were
4 asked, Mr. Slater did, about the evolution of
5 development of knowledge, but my question
6 specifically is, based upon your experience, your
7 knowledge of the medical literature, have there
8 been any known -- any new previously unknown
9 complications associated with --

10 Let me start over. I got confused on my
11 question. Let me strike it.

12 MR. OVERBY: Confused yourself.

13 MS. JONES: I confused myself.

14 MR. OVERBY: That's not good.

15 THE WITNESS: I was following.

16 BY MS. JONES:

17 Q. Have there -- are you aware of any
18 complications associated with Prolift or
19 Prolift+M that have become known to pelvic-floor
20 surgeons for the first time after the marketing
21 of Prolift?

22 A. No, I am not aware of any new
23 complications that have become evident after the
24 marketing of the Prolift+M.

1 Q. And how did the --

2 A. Prolift and Prolift+M, I'm sorry. I
3 just said Prolift+M.

4 Q. And how do the recognized
5 complications that have been reported or
6 associated with Prolift or Prolift+M compare to
7 the complications associated with any other
8 pelvic-floor repair surgery, prolapse surgery?

9 MR. SLATER: Objection. You can
10 answer.

11 THE WITNESS: Other than the -- if we
12 take any type of prolapse surgery, the
13 complications that are seen with Prolift or
14 Prolift+M are the same across the board except,
15 let's say, when you take into account the issue
16 of the mesh-related complications of, you know,
17 erosion, et cetera. However, those mesh-related
18 complications are -- can be seen in patients who
19 undergo prolapse surgery that involves mesh even
20 done in a way that doesn't involve Prolift such
21 as a sacrocolpopexy or a vaginal placement of a
22 patch of mesh, et cetera.

23 BY MS. JONES:

24 Q. Now, one of the things that Mr. Slater

1 showed you was Exhibit 8, which was the website
2 from your clinic, and I believe you testified --
3 correct me if I'm wrong -- that you had not
4 previously seen the contents of this?

5 A. I had not previously seen the content.
6 I was not involved with that part. I'm, as my
7 husband says, electronically challenged.

8 Q. Okay. Well, one of the things that he
9 asked you about was the statement that
10 transvaginally placed mesh is associated with
11 higher complication rates than traditional
12 vaginal surgery or sacrocolpopexy. In particular
13 these have been associated with serious adverse
14 events, including mesh erosion that can lead to
15 multiple surgeries to repair and may result in
16 continued pain even after mesh removal.

17 My question to you, Doctor, is, did you
18 find that to be true, one, in your practice?

19 A. I actually -- no, I did not find it to
20 be true in my practice. I personally have
21 encountered more complications and/or more
22 persistent/challenging complications following
23 sacrocolpopexy than I did following Prolift.

24 Q. Now, my second question is: Are you

1 aware of articles and studies that have compared,
2 for example, the use of transvaginal mesh with --
3 or transvaginal mesh kits -- with sacrocolpopexy
4 or others and evaluated the complication rates?

5 A. Yes, there are a number of different
6 trials that have looked at that or a number of
7 series.

8 Q. And am I correct that some of those
9 trials actually show lower complication rates in
10 the use of mesh?

11 A. Some of them do.

12 MR. SLATER: Objection. You can
13 answer.

14 THE WITNESS: Some of those trials do
15 show a lower complication rate. There also are
16 trials that are done just specifically about,
17 let's say, sacrocolpopexy that indicates, even
18 though it's not a comparison to a cohort of
19 Prolift patients, they are specifically
20 sacrocolpopexy patients, but there are some --
21 some studies indicate equivalent complication
22 issues or sometimes even higher complication
23 rates for some aspects or some complications
24 associated with sacrocolpopexies than there is

1 with a Prolift.

2 BY MS. JONES:

3 Q. And are you specifically familiar with
4 the Diwadkar study that you referenced earlier
5 today?

6 A. Yes.

7 Q. And that study compared the
8 complication rates of the different types of
9 surgeries?

10 A. Yes, it did.

11 Q. And in general what did that study
12 show with respect to those complication rates?

13 A. That Prolift or the transvaginal mesh
14 kits was not associated with an increased rate of
15 complications when compared to other Prolift --
16 other prolapse surgeries.

17 Q. I'm trying to do this quickly, and so
18 I confess to you that I'm going to ask you a
19 question that I think I've already asked, but I'm
20 not sure.

21 A. Okay.

22 Q. In your judgment were the contents of
23 the IFUs for the Prolift and the Prolift+M
24 adequate to advise pelvic-floor surgeons of the

1 risks associated with the product?

2 A. I believe so, yes.

3 MR. SLATER: You may answer.

4 BY MS. JONES:

5 Q. Now, you were asked a number of
6 questions about whether or not you based that
7 opinion upon any particular standards. Let me
8 ask you this, Doctor. Are you active in
9 professional organizations?

10 A. Yes.

11 Q. Do you have discussions with
12 colleagues and other urogynecologists and
13 pelvic-floor surgeons about their experiences
14 with surgery --

15 A. Yes.

16 Q. -- and their experiences with Prolift
17 and other mesh kits?

18 A. Yes.

19 Q. And have you attended meetings where
20 there have been presentations about those?

21 A. Yes.

22 Q. And have you reviewed the medical
23 literature with respect to risks associated with
24 that?

1 A. With Prolift? Yes.

2 Q. And you've reviewed the medical
3 literature as it relates to other pelvic-floor
4 repair surgeries?

5 A. Yes.

6 Q. And are you generally familiar with
7 the type of training that pelvic-floor surgeons
8 receive with respect to -- to pelvic-floor
9 repairs and specifically with Prolift or mesh
10 kits?

11 A. Yes, I'm aware of the type of training
12 that is done for general -- for pelvic-floor
13 surgeons who do general types of prolapse
14 surgeries across the board, all the different
15 types that we've talked about, as well as
16 specifically for Prolift.

17 Q. And have you considered all of that
18 information when you -- in determining whether or
19 not in your judgment the IFUs adequately advised
20 of the risks associated with Prolift surgery or
21 Prolift+M?

22 A. Yes, I've used all that information to
23 make my opinion that I think that there was
24 adequate information.

1 Q. As a doctor practicing medicine, doing
2 surgeries, do you generally rely upon internal
3 company documents to reach your opinions, your
4 medical opinions, on the safety or efficacy of a
5 particular product?

6 A. No, I do not.

7 Q. What do you rely upon in determining
8 whether or not in your judgment a particular
9 product or surgical procedure is safe and
10 efficacious for the patient?

11 A. I begin that type of analysis first
12 with trying to look at the underlying concept
13 behind the surgery that is being contemplated,
14 does this surgery make sense relative to what we
15 currently know about the pelvis and how it
16 behaves as well as the other surgeries that we've
17 done for, you know, previously for pelvic floor
18 or pelvic prolapse. So it's whether this is
19 based on our prior experience, based on our prior
20 knowledge, does this make sense, or if this is
21 something very different than what we typically
22 have done, is there information to support that
23 there is a reason that this would be an effective
24 and safe treatment as opposed to what we

1 traditionally do.

2 I rely on the information that is
3 communicated at our national meetings as we
4 sometimes discuss the pros and cons of early data
5 coming out or data that may or may not be present
6 looking at a particular treatment.

7 I rely upon the discussions I may have one
8 on one with my colleagues, whether at national
9 meetings or with my partners, regarding their
10 experiences with doing surgery in patients, have
11 they found a particular problem, how have they
12 addressed that particular problem, either in a
13 different type of surgery or in a Prolift
14 surgery.

15 I rely on the fact that every time I
16 operate every day of the week that I learn
17 another small amount of information of how to try
18 to treat patients more effectively. You know, I
19 evaluate my own surgeries every time I come out
20 of the operating room. I look at what the -- at
21 least the anatomic effect is, and ultimately the
22 clinical effect in my post-op care and say,
23 knowing this outcome would I have changed how I
24 approach the patient differently going forward,

1 how might I use that information for my next
2 patient to address the issues? I mean, there is
3 a whole host of different things we use in making
4 our clinical decisions regarding patient
5 management.

6 Q. And have you used all of that
7 information and the different types of
8 information in evaluating whether or not in your
9 judgment Prolift or Prolift+M were safe and
10 effective devices for use in appropriate
11 patients?

12 A. Yes, that's the information that I
13 used in making my opinions that I stated today.

14 Q. And what is your opinion with respect
15 to whether or not Prolift or Prolift+M are safe
16 and effective for use in patients?

17 A. I think, yes, that they are. I mean,
18 I see patients now who come to see me
19 postoperatively, someone even in the last week or
20 two, who was a total Prolift from, I think, 2006
21 and totally asymptomatic, very happy with the
22 results, happy that she did not have a more
23 invasive procedure or laparoscopic -- or open
24 procedure since that laparoscopy was really not

1 being done by us at that time.

2 Q. And you were asked specifically about
3 the Blandon article. Do you remember those
4 questions?

5 A. Regarding, yeah, from the Mayo Clinic
6 about dealing with the complications, et cetera,
7 yes.

8 Q. Right. And asked about whether or not
9 those complications should have been or potential
10 risks should have been warned of. In your
11 judgment were those complications in fact covered
12 by the IFU?

13 A. I believe that --

14 MR. SLATER: Objection. You can
15 answer.

16 THE WITNESS: I believe that the
17 discussion regarding being familiar with the use
18 of mesh as a pelvic surgeon and the complications
19 associated with mesh does illustrate in the
20 majority of cases the complications that have
21 been encountered with Prolift.

22 BY MS. JONES:

23 Q. Was there any evidence in this case --
24 you were asked some questions about visceral

1 injury. Was there any evidence in this case that
2 Ms. Schubert experienced a visceral injury during
3 the Prolift procedure?

4 A. During the placement of the Prolift or
5 the Prolift+M, no.

6 Q. Based upon your review of the
7 literature, the clinical experience, the
8 knowledge you have, do you believe that there was
9 sufficient clinical data to support the launch of
10 Prolift at the time it was first marketed?

11 A. Yes, I do, especially in light of the
12 state of the art at that particular time.

13 Q. And, finally, Doctor, you were asked a
14 number of questions about pelvic muscle symptoms.
15 Do you remember those? Do patients who have
16 pelvic-floor surgery not involving mesh, are they
17 at risk also for experiencing clinically
18 significant pelvic muscle symptoms?

19 A. Yes, they are.

20 MR. SLATER: Objection.

21 BY MS. JONES:

22 Q. I thank you. I think that's all I
23 have.

24 MR. SLATER: All right. I have some

1 follow-up questions. So let's launch into them
2 and we'll get done in a couple minutes.

3 EXAMINATION (resumed)

4 BY MR. SLATER:

5 Q. Doctor, let's start from the end. You
6 said that Ethicon had enough clinical data to
7 support the launch of the Prolift; is that what
8 you said?

9 A. Yes. Sorry. You're gone. Can't hear
10 you.

11 Q. You do not know what clinical data
12 Ethicon Medical Affairs relied on to support the
13 launch of the Prolift, correct?

14 A. Other than what was published in the
15 literature and whether they had additional data,
16 I don't know that.

17 Q. You don't know what data existed
18 within Ethicon other than what was published and
19 was generally available in the literature,
20 correct?

21 A. Correct, yes, the literature that was
22 from the transvaginal mesh studies, et cetera.

23 Q. Your opinion that the -- well,
24 rephrase.

1 At the time that the Prolift+M was
2 launched, other than what was publicly available,
3 you don't know what literature or -- rephrase.

4 Other than what was generally available in
5 the literature at the time the Prolift+M was
6 launched, you don't know what clinical data
7 Ethicon Medical Affairs relied on to support the
8 launch of the Prolift+M, correct?

9 A. Correct.

10 THE REPORTER: Start over again.

11 THE WITNESS: I'm sorry. We lost you
12 again.

13 BY MR. SLATER:

14 Q. In offering the opinion you offered a
15 few minutes ago that you think the Prolift is a
16 safe and effective medical device, that opinion
17 is only based on the information that you've read
18 and the things you know, correct?

19 A. Yeah, I think it's hard for me to base
20 an opinion on things that, you know --

21 Q. Let's just stick with yes or no so we
22 can get done. Okay?

23 A. Yes.

24 Q. Is the answer to my question yes?

1 A. Yes.

2 Q. To the extent that Ethicon's internal
3 documents would have information that is
4 significant to whether or not the Prolift was
5 safe and effective, the fact that you didn't see
6 that information can undercut the validity of
7 your opinion, correct? It can, right?

8 MS. JONES: Object to the form.

9 THE WITNESS: I think that it would --
10 it possibly -- it depends upon -- you know, my
11 definition of whether that data shows a problem
12 with safety and effectiveness may be different
13 than someone else who has analyzed the data and
14 says that this is a problem.

15 BY MR. SLATER:

16 Q. With regard to your opinion as to
17 whether the Prolift is safe and effective, you
18 don't know what Ethicon knew or what was in their
19 files with regard to that question other than
20 what was publicly available, so you don't know
21 how that internal information would impact on
22 your opinion, correct?

23 A. Correct.

24 Q. You don't know how Ethicon determined

1 internally that the Prolift was safe and
2 effective and could be marketed, correct?

3 A. I think -- yes.

4 Q. And the same holds true for the
5 Prolift+M, correct?

6 A. Yes.

7 Q. You mentioned earlier in the
8 deposition some animal studies with mesh.
9 Remember that?

10 A. Yes.

11 Q. You don't hold yourself out as an
12 expert with regard to how one would take the
13 results of an animal study, for example, putting
14 mesh in a rat for 91 days and how that would
15 correlate to the use of mesh in a female pelvis,
16 correct?

17 A. I do not consider myself an expert in
18 that research area, no.

19 Q. -- forming any opinions based upon the
20 preclinical testing that you may have seen with
21 regard to the mesh, correct?

22 A. The first part is -- I missed because
23 you were gone, the first part of the question.

24 Q. You're not forming any opinions based

1 on the preclinical testing that you may have
2 seen, correct?

3 A. I have used the preclinical
4 information of the animal studies, both at
5 Ethicon and in other animal studies, as part of
6 my evaluation of mesh in and of itself, yes, and
7 how it -- and how it works within --

8 Q. I think this is going to disconnect
9 me. I'm getting very -- okay. We're good.

10 (The record was read by the reporter.)

11 BY MR. SLATER:

12 Q. The bottom line is, you're not holding
13 yourself out as an expert with regard to the
14 question of how does the preclinical testing with
15 the mesh translate to whether or not the mesh
16 would be safe or effective in a female pelvis or
17 vagina, correct?

18 A. I'm not sure that I totally understand
19 your question, in which direction, but, you know,
20 the information that's in the animal studies is
21 part of what is used to begin to evaluate the use
22 of any product in itself. It doesn't necessarily
23 mean that the response in the animal is going to
24 be exactly the same as the response in the

1 patient, but since we in our field do not have an
2 established animal model for prolapse, it is
3 difficult for us to do specific animal studies
4 that we know are going to be absolutely
5 correlating, but it is a starting point in
6 looking at the response of materials in vivo.

7 Q. There is no animal study where you're
8 saying that animal study in my opinion proves to
9 a reasonable degree of medical certainty that the
10 mesh used in the Prolift or the Prolift+M would
11 be safe and effective in use in the female
12 pelvis, correct?

13 A. I don't think there is a study that I
14 can specifically cite that makes that conclusion,
15 you know, in an absolute form.

16 Q. With regard to the Prolift itself, you
17 were not convinced that it was the right answer
18 for more than half your patients during the time
19 you used the Prolift, correct?

20 A. We've had this discussion previously.
21 I cannot tell you --

22 Q. It's a simple yes or no question.

23 A. No, it's not a yes or no question. I
24 can't give you a yes or no answer.

1 Q. There are women for whom the Prolift
2 would not be the appropriate treatment, correct?

3 A. Yes, that's correct.

4 Q. And the group of women for which the
5 Prolift would not be the correct treatment is a
6 larger group of women than just women who are
7 either pregnant or considering getting pregnant
8 in the future, correct?

9 A. I think there are other patients that
10 it may not be the best choice for them, yes.

11 Q. Assuming no other questions are asked,
12 that is the end of my questioning of you.

13 MS. JONES: We're done.

14 VIDEO SPECIALIST: The time now is
15 6:06. This deposition has concluded.

16 THE REPORTER: Do you want your
17 previous order, regular delivery and email?

18 MR. SLATER: I need the rough and then
19 however they normally send it, but I'll need a
20 rough for this.

21 THE REPORTER: And regular delivery on
22 the final?

23 MS. JONES: Me too.

24

1 (Proceedings concluded.)

2 //

3 (Signature having not been waived, the
4 deposition of NICOLETTE HORBACH, M.D. adjourned
5 at 6:06 p.m.)

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1 ACKNOWLEDGMENT OF DEPONENT

2

3 I, NICOLETTE HORBACH, M.D., do hereby
4 acknowledge that I have read and examined the
5 foregoing testimony and that the same is a true,
6 correct and complete transcription of the
7 testimony given by me, with the exception of the
8 noted corrections, if any, appearing on the
9 attached errata page.

10

11

12 _____
DATE NICOLETTE HORBACH, M.D.

13

14

15

16 Subscribed and sworn to before me this _____ day
17 of _____, 20____.

18 _____ (Notary Public)

19 My Commission expires: _____

20

21

22

23

24

Nicolette S. Horbach, M.D.

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1 C E R T I F I C A T E

2

3 I, LINDA S. KINKADE, Registered

4 Diplomat Reporter, Certified Realtime Reporter,

5 Registered Merit Reporter, Certified Shorthand

6 Reporter, and Notary Public, do hereby certify

7 that prior to the commencement of examination the

8 deponent herein was duly sworn by me to testify

9 truthfully under penalty of perjury.

10 I FURTHER CERTIFY that the foregoing is a

11 true and accurate transcript of the proceedings

12 as reported by me stenographically to the best of

13 my ability.

14 I FURTHER CERTIFY that I am neither

15 counsel for nor related to nor employed by any of

16 the parties to this case and have no interest,

17 financial or otherwise, in its outcome.

18 IN WITNESS WHEREOF, I have hereunto set my

19 hand and affixed my notarial seal this 27th day

20 of August 2013.

21 My commission expires: July 31, 2017

22 _____

23 NOTARY PUBLIC IN AND FOR

24 THE DISTRICT OF COLUMBIA

Nicolette S. Horbach, M.D.

1 C E R T I F I C A T E

2

3 I, LINDA S. KINKADE, Registered
4 Diplomate Reporter, Certified Realtime Reporter,
5 Registered Merit Reporter, Certified Shorthand
6 Reporter, and Notary Public, do hereby certify
7 that prior to the commencement of examination the
8 deponent herein was duly sworn by me to testify
9 truthfully under penalty of perjury.

10 I FURTHER CERTIFY that the foregoing is a
11 true and accurate transcript of the proceedings
12 as reported by me stenographically to the best of
13 my ability.

14 I FURTHER CERTIFY that I am neither
15 counsel for nor related to nor employed by any of
16 the parties to this case and have no interest,
17 financial or otherwise, in its outcome.

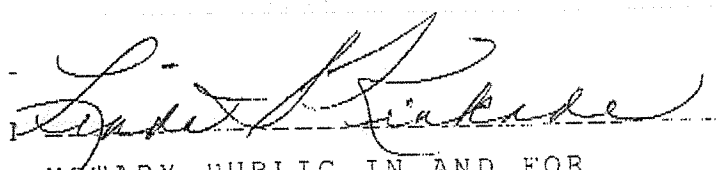
18 IN WITNESS WHEREOF, I have hereunto set my
19 hand and affixed my notarial seal this 27th day
20 of August 2013.

21 My commission expires: July 31, 2017

22

23

24


NOTARY PUBLIC IN AND FOR
THE DISTRICT OF COLUMBIA